## Japanese Medical Device Nomenclature (JMDN) Definition

<table>
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<tr>
<th>Japanese Medical Device Nomenclature (JMDN)</th>
<th>Definition</th>
<th>JMDN Code</th>
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<th>QMS Requirements</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reusable ultrasound probe for central nerve/central cardiovascular system surgery</td>
<td>A probe used for surgery of the central nerve/central circulatory system. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take images of localized surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. As a part of the design of transducer casing or housing assembly, the route to introduce the biopsy needle may be incorporated. This device is reusable.</td>
<td>40770004</td>
<td>IV</td>
<td>7-⑤, 7-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Polygraph with cardiac catheter</td>
<td>A device to test hemodynamics in each site of the heart by inserting the catheter into the heart. The device includes the catheter.</td>
<td>70052004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Vessel diameter measuring system with cardiac catheter</td>
<td>A device with a cardiac catheter to measure the balloon diameter and the blood vessel diameter. The catheter is inserted into the coronary artery or other vessel. Then, the balloon located near the tip of catheter is dilated, and the inner pressure obtained by the tip of catheter are sent to the dedicated external measuring device. The data are processed in the measuring device.</td>
<td>70053000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Vessel temperature measuring system with cardiac catheter</td>
<td>A device with a cardiac catheter to measure vascular wall temperature. The catheter is inserted into the stenotic segment of the coronary artery or other vessel, and the temperature sensor located near the tip of catheter is pressed against the vascular wall for measurement. The catheter and the temperature measuring device are connected using a dedicated connector.</td>
<td>70054000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Cortical electrode</td>
<td>A conductor used on the surface of or deep inside the brain temporarily or for a short period in order to stimulate the brain or record cerebral electrical activity.</td>
<td>32545000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cardiac/central nerve stimulator</td>
<td>A probe for the heart and central nervous system specifically designed to be used with a stimulator.</td>
<td>36957004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Flexible angioscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the venous or arterial lumen. It is percutaneously inserted. This product is a fiberscope, in which images are transmitted through a fiber optic bundle.</td>
<td>34010000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible arterioscope</td>
<td>An endoscope used to observe, diagnose and treat (in some cases) conditions of coronary arteries, peripheral and intracardiac structures. The insertion section, which is made of flexible materials, is inserted into the vessel to be examined. A fiber optic bundle is used for the image transmission system.</td>
<td>34855000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Instrument</td>
<td>Description</td>
<td>CPC Code</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
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</tr>
<tr>
<td>Flexible neuroscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the central nervous system. The device is inserted through an opening in the skull created in advance. The shape of the insertion section of the product changes according to that of the body cavity. The image transmission system comprises a fiber optic bundle.</td>
<td>37181000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible myeloscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the spinal cord. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.</td>
<td>70105000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible lumboscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the lumbar spine. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.</td>
<td>70108000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible spineoscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the spine. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.</td>
<td>70113000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video myeloscope</td>
<td>An endoscope used to observe, diagnose, and treat spinal cord conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.</td>
<td>70122000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video lumboscope</td>
<td>An endoscope used to observe, diagnose, and treat lumbar conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.</td>
<td>70125000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video spineoscope</td>
<td>An endoscope used to observe, diagnose, and treat spinal column conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.</td>
<td>70130000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video angioscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the venous or arterial lumen. Inserted percutaneously. This device is a videoscope that provides images via a charge coupled device (CCD) chip or other imaging components.</td>
<td>70140000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video neuroscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the central nervous system. It is inserted through an opening in the skull created in advance. The insertion section changes its shape corresponding to the shape of the body cavity. A videoscope is equipped with a charge-coupled device (CCD) chip for image transmission.</td>
<td>70142000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video arterioscope</td>
<td>An endoscope used to observe, diagnose and treat (in some cases) conditions of coronary arteries, peripheral and intracardiac structures. Inserted into the target vessel. The insertion part is flexible. This is a videoscope equipped with a charge coupled device (CCD) chip that serves as an image transmission system.</td>
<td>70144000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid myeloscope</td>
<td>An endoscope used to observe, diagnose, and treat conditions of the spinal cord. The device is inserted through an artificial opening. This product is a rigid endoscope, by which the insertion section resists the body cavity. Relay lens optics are used for image transmission. Some types use a fiber optic bundle for image transmission.</td>
<td>35200009</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid lumboscope</td>
<td>An endoscope used in direct contact with the central nervous system to observe, diagnose, and treat lumbar conditions. Inserted from an artificial opening. This device is a rigid endoscope, by which the insertion section resists the body cavity, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.</td>
<td>35568009</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>ANI Code</td>
<td>IVD</td>
<td>Category</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td><strong>Rigid neuroscope</strong></td>
<td>An endoscope used to observe, diagnose, and treat conditions of the central nervous system. The device is inserted through an opening in the skull created in advance. This product has a rigid insertion section. Relay lens optics are used for image transmission, and some types of products have a fiber optic bundle.</td>
<td>36904000</td>
<td>IV</td>
<td>7-5</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Single-use rigid neuroscope</strong></td>
<td>A single-use endoscope to observe, diagnose, and treat central nervous system conditions. Inserted via a hole opened in the cranium in advance. The insertion part is rigid, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.</td>
<td>70148000</td>
<td>IV</td>
<td>7-5</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Rigid spinoscope</strong></td>
<td>An endoscope used to observe, diagnose and treat spinal column conditions. Inserted from an artificial opening. The insertion part is rigid, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.</td>
<td>70152000</td>
<td>IV</td>
<td>7-5</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Transseptal needle</strong></td>
<td>A needle for puncturing the atrial septum (oval fossa) in order to form a path through which to insert a catheter for vascular diagnosis/treatment. The needle is to be percutaneously inserted and advanced from the right atrium to the left atrium. This puncture needle is introduced percutaneously into the right atrium using a catheter introducer.</td>
<td>70209000</td>
<td>IV</td>
<td>6-5</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable cardiac aspiration needle</strong></td>
<td>A long, thin, sharp, hollow needle used to aspirate (remove) fluid from pericardial cavity (pericardiocentesis). Usually it is a rigid needle long enough, i.e., 10–18 cm, to pierce through the pericardium. It has a short bevel tip. This device is reusable.</td>
<td>44136000</td>
<td>IV</td>
<td>6-5</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use cardiac aspiration needle</strong></td>
<td>A long, thin, sharp, hollow needle used to aspirate (remove) fluid from pericardial cavity (pericardiocentesis). Usually it is a rigid needle long enough, i.e., 10–18 cm, to pierce through the pericardium. It has a short bevel tip. This device is for single-use.</td>
<td>44135000</td>
<td>IV</td>
<td>6-5</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Catheter for central venous</strong></td>
<td>A flexible tube that is usually introduced into a neck or thoracic vein, and inserted into the superior vena cava for purposes that include infusion of substances, aspiration of blood, and monitoring blood pressure. The proximal end of the tube is fixed to the patient for long-term use. Some types of product are cuffed.</td>
<td>10729100</td>
<td>IV</td>
<td>8-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Catheter for antimicrobial central venous</strong></td>
<td>A flexible antibacterial tube usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff. In some types, antibacterial materials are used only for the cuff.</td>
<td>10729200</td>
<td>IV</td>
<td>7-6,13</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Catheter for heparin-coated central venous</strong></td>
<td>A flexible heparin-coated tube usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff.</td>
<td>10729300</td>
<td>IV</td>
<td>8-2,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Urokinase-coated central venous catheter</strong></td>
<td>A flexible tube with urokinase usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff. It contains biological urokinase.</td>
<td>10729400</td>
<td>IV</td>
<td>8-2,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Central venous catheterization kit</strong></td>
<td>A kit containing equipment for central venous catheterization. Typically, a catheter and an introducer needle are included in a kit.</td>
<td>16615110</td>
<td>IV</td>
<td>8-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Heparin-coated central venous catheterization kit</strong></td>
<td>A heparin-coated package that contains devices to be used when inserting a central venous catheter. Usually it includes a catheter and an introducer.</td>
<td>16615200</td>
<td>IV</td>
<td>8-2,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Category</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Central venous catheterization kit with urokinase</td>
<td>A package that contains devices to be used when inserting a central venous catheter with urokinase. Usually it includes a catheter and an introducer.</td>
<td>16615300</td>
<td>IV</td>
<td>8-2,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Antimicrobial central venous catheterization kit</td>
<td>An antibacterial package that contains devices to be used when inserting a central venous catheter. Usually it includes a catheter and an introducer.</td>
<td>16615400</td>
<td>IV</td>
<td>7-13</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Peripheral insertion central venous catheter</td>
<td>A flexible tube that is introduced into a peripheral vein in order to infuse a substance, aspirate blood or monitor blood pressure. For insertion into the upper body, the tube is inserted via the axillary vein into the superior vena cava. For insertion into the lower body, the tube is placed in the inferior vena cava. The proximal end of the tube is fixed to the patient for long-time use.</td>
<td>36257100</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated peripheral insertion central venous catheter</td>
<td>A flexible heparin-coated tube that is introduced into a peripheral vein in order to infuse a substance, aspirate blood or monitor blood pressure. For insertion into the upper body, the tube is inserted via the axillary vein into the superior vena cava. For insertion into the lower body, the tube is placed in the inferior vena cava. The proximal end of the tube is fixed to the patient for long-time use.</td>
<td>36257200</td>
<td>IV</td>
<td>7-14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Peripheral insertion central venous catheterization kit</td>
<td>A kit containing equipment for inserting a peripherally inserted central venous catheter. Usually, a catheter and an introducer needle are included in a kit.</td>
<td>16615120</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Vascular perfusion catheter</td>
<td>A flexible tube to supply blood to the vascular bed. The device is used mainly to protect organs (e.g., cerebral and abdominal organs) when circulation is totally or partially suspended, or during surgery or catheterization (e.g., arterial surgery, carotid angioplasty).</td>
<td>10739100</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated vascular perfusion catheter</td>
<td>A flexible heparin-coated tube to supply blood to the vascular bed. The device is used mainly to protect organs (e.g., cerebral and abdominal organs) when circulation is totally or partially suspended, or during surgery or catheterization (e.g., arterial surgery, carotid angioplasty).</td>
<td>10739200</td>
<td>IV</td>
<td>7-14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Coronary artery cannula</td>
<td>A semi-rigid tube to be inserted into the coronary artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.</td>
<td>34896100</td>
<td>IV</td>
<td>6-5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated coronary artery cannula</td>
<td>A semi-rigid heparin-coated tube to be inserted into the coronary artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.</td>
<td>34896200</td>
<td>IV</td>
<td>6-5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Vena cava cannula</td>
<td>A semi-rigid or rigid tube to be inserted into the vena cavae and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.</td>
<td>34904100</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated vena cava cannula</td>
<td>A semi-rigid or rigid heparin-coated tube to be inserted into the vena cavae and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.</td>
<td>34904200</td>
<td>IV</td>
<td>7-14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Coronary perfusion catheter</td>
<td>A flexible tube used for coronary perfusion and fluid lavage.</td>
<td>34914100</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated coronary perfusion catheter</td>
<td>A flexible heparin-coated tube used for coronary perfusion and fluid lavage.</td>
<td>34914200</td>
<td>IV</td>
<td>7-14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aortic cannula</td>
<td>A semi-rigid tube to be inserted into the aorta, and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.</td>
<td>35565100</td>
<td>IV</td>
<td>7-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Applicable Ranges</td>
<td>Applicability</td>
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</tr>
<tr>
<td><strong>Heparin-coated aortic cannula</strong></td>
<td>A semi-rigid heparin-coated tube to be inserted into the aorta, and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.</td>
<td>35565200</td>
<td>IV (7\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ventricular cannula</strong></td>
<td>A semi-rigid or rigid metal or plastic tubular device to be inserted into the ventricle or atrium usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path to inject/discharge fluid, or as a guide path through which a catheter or surgical device can be inserted. This device is for single-use.</td>
<td>35891200</td>
<td>IV (6\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heparin-coated ventricular cannula</strong></td>
<td>A semi-rigid or rigid, heparin-coated metal or plastic tubular device to be inserted into the ventricle or atrium usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path to inject/discharge fluid, or as a guide path through which a catheter or surgical device can be inserted. This device is for single-use.</td>
<td>36109200</td>
<td>IV (6\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Coronary sinus cannula</strong></td>
<td>A semi-rigid tube to be inserted into the coronary sinus in order to perform retrograde coronary perfusion/cardioplegia during cardiopulmonary bypass. The device may be equipped with a self-expandable low pressure balloon, which is usually used to cause retrograde blood flow in the coronary artery in the event of a contingent air embolism in the coronary artery. This device is for single-use.</td>
<td>36109200</td>
<td>IV (6\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heparin-coated coronary sinus cannula</strong></td>
<td>A semi-rigid heparin-coated tube to be inserted into the coronary sinus in order to perform retrograde coronary perfusion/cardioplegia during cardiopulmonary bypass. The device may be equipped with a self-expandable low pressure balloon, which is usually used to cause retrograde blood flow in the coronary artery in the event of a contingent air embolism in the coronary artery. This device is for single-use.</td>
<td>36109200</td>
<td>IV (6\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cardiac catheter-tip electrode</strong></td>
<td>A conductor installed at one end of a flexible tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing and defibrillation.</td>
<td>11434100</td>
<td>IV (7\llcorner)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heparin-coated cardiac catheter-tip electrode</strong></td>
<td>A conductor installed at one end of a flexible heparin-coated tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing.</td>
<td>11434200</td>
<td>IV (7\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ventricular cardiac catheter</strong></td>
<td>A flexible tube with a specifically shaped tip designed to be inserted into the chambers of the heart such as the left and right ventricles. The distal end may have a hole in the tip or several side holes. The tube is inserted into a peripheral vessel, and the distal end is positioned in the left or right ventricle according to the ventriculography required.</td>
<td>17613000</td>
<td>IV (6\llcorner, 7\llcorner)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Thermal dilution catheter</strong></td>
<td>A flexible tube equipped with a probe that monitors cardiac output by using thermodilution method.</td>
<td>34925100</td>
<td>IV (7\llcorner)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heparin-coated thermal dilution catheter</strong></td>
<td>A flexible heparin-coated tube equipped with a probe that monitors cardiac output by using thermodilution method.</td>
<td>34925200</td>
<td>IV (7\llcorner, 14)</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pacing cardiac catheter</strong></td>
<td>A flexible tube equipped with an electrode on the distal end. The electrode is inserted into the heart to control the heart rate.</td>
<td>35854110</td>
<td>IV (8\llcorner)</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>Description</td>
<td>Details</td>
<td>Code</td>
<td>Class</td>
<td>Intended Use</td>
<td>Applicable</td>
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<tr>
<td>Pacing cardiac balloon catheter</td>
<td>A tube with flexible balloon equipped with an electrode on the distal end. The electrode is inserted in the heart to control the heart rate.</td>
<td>35854120</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated pacing cardiac balloon catheter</td>
<td>A flexible heparin-coated tube with balloon equipped with an electrode on the distal end. The electrode is inserted into the heart to control the heart rate.</td>
<td>35854200</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter for central circulatory angiography</td>
<td>A flexible tube designed for injection of a contrast agent into vessels in the central cardiovascular system for vascular imaging in the target section of the body.</td>
<td>10688104</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter for central circulatory arterial</td>
<td>A flexible tube designed that is usually inserted through arteries of the central circulatory system for infusion/suction. In order to measure arterial blood pressure continuously, the device is usually connected to an oscilloscope.</td>
<td>10689104</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter for heparin-coated central circulatory arterial</td>
<td>A flexible, heparin-coated tube designed that is usually inserted through the arteries of the central circulatory system for infusion/suction. In order to measure arterial blood pressure continuously, the device is usually connected to an oscilloscope.</td>
<td>10689204</td>
<td>IV</td>
<td>7-③, 14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central circulatory arterial microflow catheter</td>
<td>A flexible tube to be inserted into the circulatory system in order to accurately measure the blood flow and pressure in arteries of the central circulatory system.</td>
<td>10691004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central circulatory transducer-tip catheter</td>
<td>A catheter with a microminiature pressure transducer built into the distal end. When inserted into a blood vessel of the central circulatory system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.</td>
<td>15071104</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated central circulatory transducer-tip catheter</td>
<td>A heparin-coated catheter with a microminiature pressure transducer built into the distal end. When inserted into a blood vessel of the central circulatory system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.</td>
<td>15071204</td>
<td>IV</td>
<td>7-③, 14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Guiding intravascular catheter for central circulatory system</td>
<td>A flexible tube for a conduit through which a catheter or a guidewire is inserted to perform percutaneous endovascular surgery in the central circulatory system.</td>
<td>17846104</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated central circulatory guiding intravascular catheter</td>
<td>A flexible heparin-coated tube used as a conduit to insert a balloon catheter and guidewire in percutaneous endovascular surgery in the central circulatory system.</td>
<td>17846223</td>
<td>IV</td>
<td>6-③, 14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central nervous system transducer-tip catheter</td>
<td>A catheter with a pressure transducer built into the distal end. When inserted into the central nervous system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.</td>
<td>70271000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Spinal contact pressure monitoring kit</td>
<td>A kit containing devices used to measure blood pressure and cerebrospinal pressure invasively, in particular, devices that include domes and tubes and come into contact with the spinal column.</td>
<td>70272000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central circulatory cardiac output measurement kit</td>
<td>A kit that includes tube to measure cardiac output based on the changes in arterial pressure wave forms by measuring changes in blood flow in the blood vessels of the central circulatory system.</td>
<td>70274000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pulmonary artery catheter</td>
<td>A flexible tube with a dilation balloon at the distal end that is advanced from the superior and inferior vena cava into the pulmonary artery to measure pulmonary arterial pressure or perform pulmonary angiography.</td>
<td>35889000</td>
<td>IV</td>
<td>6-⑤, 7-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intravascular optical coherence tomography catheter</td>
<td>A catheter and a guide wire used to observe a cross section of blood vessels using an optical fiber by light. For instance, optical coherence tomography visualizes internal microscopic structure of the tissues without physical invasion of the outer protective layers. This utilizes the nature of light that penetrates and is reflected at various degrees according to the type of the tissue.</td>
<td>70275000</td>
<td>IV</td>
<td>6-⑤,10-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Valve dilation catheter guidewire and stylet</td>
<td>A guide wire (only the pre-shaped device is included) and a stylet used to guide a catheter for valve dilation or valve replacement to the target site in the heart.</td>
<td>70276000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Coronary sinus blood collection catheter</td>
<td>A tube and a catheter used to collect blood from the coronary sinus (CS). The tip comes in various configurations that allow approaches from the femoral region or superior vena cava etc.</td>
<td>70277000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cardiac catheterization kit</td>
<td>A kit containing equipment used for inserting a cardiac catheter into the ventricle, atrium, or cardiac blood vessels. The kit includes equipment used for the central cardiovascular system.</td>
<td>10598000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Catheter for central circulatory embolectomy catheter</td>
<td>A flexible tube designed to remove coagulated blood and other cellular components that could occlude the blood vessel of the central circulatory system. The device is not only used to remove occlusions in natural blood vessels, but also to remove occlusions in arteries and access grafts for hemodialysis.</td>
<td>10714004</td>
<td>IV</td>
<td>6-⑤,7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Central circulatory thrombectomy vibration catheter</td>
<td>A flexible tube with a vibrating tip to disrupt the thrombus in blood vessels of the central circulatory system into pieces small enough to be absorbed and eliminated. Introduced percutaneously or transluminally via the arterial wall.</td>
<td>70283000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cerebral thrombectomy vibration catheter</td>
<td>A flexible tube with a vibrating tip to disrupt the thrombus in the cerebral artery into pieces small enough to be absorbed and eliminated. Introduced percutaneously or transluminally via the arterial wall.</td>
<td>70284000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Septostomy catheter</td>
<td>A catheter with a balloon or a blade to be used for atrial septostomy.</td>
<td>10747000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Catheter for balloon dilatation angioplasty</td>
<td>A flexible tube for dilation of a narrowed vessel or dilation after stent placement in the vessel (an artery, vein, or shunt), except for coronary blood vessels or intracranial cerebral vessels, by controlled inflation and deflation of a balloon. The device usually consists of a double-lumen catheter with a balloon at the distal end. Some catheters have channels for pressure measurement or delivery of an angiographic agent, or have a balloon with blades, wire, or the like.</td>
<td>17184014</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Catheter for coronary balloon dilatation angioplasty</td>
<td>A flexible tube used for dilation of a narrowed coronary artery vessel by controlled inflation of a dilating balloon. The device usually consists of a double-lumen catheter with a balloon at the distal end. Some catheters have channels for pressure measurement or delivery of an contrast agent. Some catheters have a balloon with blades, wire etc.</td>
<td>17184024</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Catheter for cerebral balloon dilatation angioplasty</td>
<td>A flexible tube used to dilate stenotic cerebral arteries by controlling the degree of balloon dilation. The device usually consists of dual lumens with a balloon at the distal end. Some have side holes for pressure measurement or delivery of contrast agent.</td>
<td>17184034</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Laser angioplasty catheter</td>
<td>A flexible tube equipped with optical fibers for vaporizing atherosclerotic plaques directly by a laser in constricted or occluded blood vessels.</td>
<td>17185000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Balloon dilatation valvuloplasty catheter</td>
<td>A flexible tube with a balloon used for cardiac valvuloplasty and repair surgery.</td>
<td>17453000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Atherectomy angioplasty catheter</strong></td>
<td>A flexible tube and a catheter to remove (resection, perforation, pulverization, or cutting) atherosclerotic plaques percutaneously or transluminally via the arterial wall. The vascular wall becomes smooth after the removal, with the stenosis virtually eliminated.</td>
<td>17519000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Balloon dilatation coronary perfusion angioplasty catheter</strong></td>
<td>A flexible tube to dilate stenotic cerebral arteries by controlling the degree of balloon dilation. The device has holes in the proximal and distal parts of the balloon. In order to prevent circulatory disorders in cardiac muscles, the device ensures blood flow in the distal coronary artery during balloon dilation.</td>
<td>17521000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Catheter guide wire for cardiac/central circulatory system</strong></td>
<td>A device for adjusting the position of, or supporting the delivery of a catheter. The device is commonly made of coated or uncoated stainless steel, and coating facilitates its movement in the cardiovascular and central vascular systems.</td>
<td>35094114</td>
<td>IV</td>
<td>6-⑤,7-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Heparin-coated cardiac/central circulatory catheter guidewire</strong></td>
<td>A device used to adjust the position of the catheter and lead wire and assist movement. It is made of heparin-coated stainless steel, or plastic. The coating facilitates movement in the heart and central circulatory system, preventing the thrombus formation.</td>
<td>35094214</td>
<td>IV</td>
<td>6-⑤,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Central nervous system catheter guidewire</strong></td>
<td>A device used to adjust the position of the catheter and lead wire and assist movement. Generally, it is made of stainless steel or plastic either coated or uncoated. The coating facilitates movement in the central nervous system.</td>
<td>35094124</td>
<td>IV</td>
<td>6-⑤,7-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Central circulatory intravascular embolization prosthesis</strong></td>
<td>An artificial device to be used to promote thrombus formation or to block the blood flow in arteries or veins of the central circulatory system for therapeutic purposes.</td>
<td>35449004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Cardiac catheter-tip flow transducer</strong></td>
<td>A cardiac catheter with a microminiature transducer built into the distal end to detect and measure blood flow. When inserted into a blood vessel, its mechanical and electrical characteristics change according to the changing blood flow. The change is transmitted to the base unit, and displayed.</td>
<td>36040104</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Heparin-coated cardiac catheter-tip flow transducer</strong></td>
<td>A heparin-coated cardiac catheter with a microminiature transducer built into the distal end to detect and measure blood flow. When inserted into a blood vessel, its mechanical and electrical characteristics change according to the changing blood flow. The change is transmitted to the base unit, and displayed.</td>
<td>36040204</td>
<td>IV</td>
<td>7-⑥,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Atherectomy ablative angioplasty catheter</strong></td>
<td>A flexible tube to remove hardened, calcified atherosclerotic plaques percutaneously or transluminally via the arterial wall by pulverizing atheroma into pieces small enough to be absorbed and eliminated through the reticuloendothelial system.</td>
<td>36073000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Cardiovascular catheter guidewire</strong></td>
<td>A device used to adjust the position of a coronary artery catheter and assist movement. Both coated and uncoated devices are available. The coating facilitates movement in the blood vessels. The device is usually made of metal but some are partially made of plastic.</td>
<td>70287009</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Central circulatory therapeutic tube and catheter</strong></td>
<td>A tube and catheter used for thrombus removal and vasodilation in the central circulatory system. With an introducer and guide wire, the device is also used for treatment in the blood and lymph vessels.</td>
<td>70288000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Central circulatory intravascular ultrasound catheter</strong></td>
<td>A catheter that incorporates ultrasound for diagnosis in the blood vessels of the central circulatory system. The device is equipped with a transducer at the proximal end of catheter that sends and receives ultrasound signals.</td>
<td>70289004</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>70290100</td>
<td>IV</td>
<td>6-①</td>
<td>applicable</td>
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<tr>
<td>Cardiovascular suture assist tube</td>
<td>A device temporarily placed in the blood vessel during AC bypass surgery in order to secure blood flow during suturing. Generally, the vessel insertion part is either a shunt or sheet. Inseters made of various materials are used for some devices.</td>
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<tr>
<td>Heparin-coated cardiovascular suture assist tube</td>
<td>A heparin-coated device temporarily placed in the blood vessel during AC bypass surgery in order to secure blood flow during suturing. Generally, the vessel insertion part is either a shunt or sheet. Inseters made of various materials are used for some devices.</td>
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<tr>
<td>Coronary artery occluder</td>
<td>A device used to temporarily ligate and fix the coronary artery using a snare during the off-pump CABG. This device is for single-use.</td>
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<tr>
<td>Retractable balloon</td>
<td>A device is inserted into the lower posterior part of the heart, and the balloon is dilated in order to alter the position of the heart and obtain exposure of the coronary artery during the off-pump CABG. This device is for single-use.</td>
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<tr>
<td>Catheter for coronary wire-support</td>
<td>A catheter for secure a path for inserting a guide wire in percutaneous coronary angioplasty in patients with completely occluded stenosis in the coronary artery through which a guide wire is difficult to pass.</td>
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<tr>
<td>Central circulatory microcatheter</td>
<td>A small-diameter catheter that can be used for a procedure, such as superselective angiography, which is performed by selecting a particular vessel in the central circulatory system. It has a function at the distal end to improve visibility so that the position can be confirmed under fluoroscopy.</td>
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<tr>
<td>Fibroptic oximetry catheter</td>
<td>A flexible tube with a bundle of optical fibers built in that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation. This is used with an oximeter.</td>
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<tr>
<td>Heparin-coated fibroptic oximetry catheter</td>
<td>A flexible heparin-coated tube with a bundle of optical fibers built in that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation. This is used with an oximeter.</td>
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<tr>
<td>Heparin-coated fibroptic oximetry catheter with thermistor</td>
<td>A flexible heparin-coated tube with a temperature monitoring thermistor and a bundle of optical fibers (that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation) built in. This is used with an oximeter.</td>
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<tr>
<td>Intravascular occlusion for central circulatory system</td>
<td>A flexible tube with a dilation balloon at the tip (some are removable) for to block blood vessels of the central circulatory system.</td>
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<tr>
<td>Balloon dilatation heated angioplasty catheter</td>
<td>A dedicated flexible tube with an expandable balloon designed to provide thermal energy to the site of the angioplasty in the coronary artery.</td>
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<tr>
<td>Balloon pumping catheter</td>
<td>A catheter for the balloon pump of an auxiliary circulation device, and a balloon catheter to be placed in an artery for auxiliary circulation to the heart. The circulation is assisted by synchronizing the dilation/contraction of the balloon at the tip with the pulse. Used for severe cardiac failure such as cardiogenic shock after acute myocardial infarction, before/during/after high-risk cardiac catheterization and thoracotomy. The device is often used in emergencies in the former cases, and for scheduled use in the latter cases. This device is for single-use.</td>
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<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Applicable</td>
<td>Other</td>
<td></td>
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<tr>
<td>Catheter for cardiac ablation</td>
<td>A powered flexible tube designed to surgically remove or partially alter the heart region.</td>
<td>35855000</td>
<td>IV</td>
<td>6-③,7-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Oximetry catheter with balloon</td>
<td>A flexible tube with an expandable balloon at the distal end to monitor oxygen saturation in the right heart or pulmonary artery using an optical fiber.</td>
<td>35856100</td>
<td>IV</td>
<td>7-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated oximetry catheter with balloon</td>
<td>A flexible heparin-coated tube with an expandable balloon at the distal end to monitor oxygen saturation in the right heart or pulmonary artery using an optical fiber.</td>
<td>35856200</td>
<td>IV</td>
<td>7-⑥,14 applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Radio-frequency thermal angioplasty catheter</td>
<td>A flexible tube that uses high frequency energy to heat a metal cap wound around the distal end of the tube or a metal belt around the tube in order to evaporate or melt the atherosclerotic plaque in blood vessels. The high frequency energy is delivered from an electric scalpel unit connected to a device that adjusts the energy level.</td>
<td>36074000</td>
<td>IV</td>
<td>6-⑤ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Infusion catheter for coronary artery</td>
<td>A flexible tube for to locally infuse drugs (e.g., heparin) into a coronary vascular structure. Usually, it consists of a dual-lumen tube. While a drug solution being is infused into an artery from one lumen to immerse the vascular wall, the other lumen serves as a path for the guide wire. Furthermore, the device can also be used for thrombolysis in cardiovascular system.</td>
<td>36205000</td>
<td>IV</td>
<td>6-④,6-⑤ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Thermal dilution catheter with oxygen saturation monitor</td>
<td>A flexible tube with a dilation balloon at the distal end that floats in the pulmonary artery when measuring pulmonary arterial pressure and mixed venous oxygen saturation.</td>
<td>36218100</td>
<td>IV</td>
<td>7-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated thermal dilution catheter with oxygen saturation monitor</td>
<td>A flexible heparin-coated tube with a dilation balloon at the distal end that floats in the pulmonary artery when measuring pulmonary arterial pressure and mixed venous oxygen saturation.</td>
<td>36218200</td>
<td>IV</td>
<td>7-⑥,14 applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Cerebral perfusion catheter</td>
<td>A flexible catheter designed for retrograde cerebral perfusion with cool oxygenated blood. The catheter is a 2-lumen type with several side holes and a balloon at the tip. The catheter is percutaneously inserted into the internal jugular vein so that the side holes stay in the vein. In the case of a responsive subclavian venous valve, the balloon at the tip of catheter, which is used for cerebral perfusion, is dilated to occlude the drainage vein (superior vena cava and aygous vein). The catheter is used to protect the brain during deep hypothermic circulatory arrest in thoracic aortic surgery.</td>
<td>37696000</td>
<td>IV</td>
<td>6-⑤ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Central nervous multi-lumen catheter</td>
<td>A flexible 2-lumen (or multiple-lumen) tube for the central nervous system used to infuse fluid into the body or drain fluid.</td>
<td>32330314</td>
<td>IV</td>
<td>7-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Central circulatory multi-lumen catheter</td>
<td>A flexible 2-lumen (or multiple-lumen) tube for the central circulatory system used to infuse fluid into the body or drain fluid.</td>
<td>32330324</td>
<td>IV</td>
<td>7-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Cerebrospinal catheter</td>
<td>A flexible tube used to remove and transfer spinal fluid from the central nervous system.</td>
<td>10704000</td>
<td>IV</td>
<td>8-② applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Implantable cerebrospinal fluid reservoir</td>
<td>A device to retain spinal fluid when infusing drug solution and collecting spinal fluid. A catheter is connected to access cerebral ventricles and marrow cavity.</td>
<td>15874004</td>
<td>IV</td>
<td>8-⑥ applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Cerebrospinal fluid catheter</td>
<td>A flexible tube used to drain spinal fluid.</td>
<td>16133000</td>
<td>IV</td>
<td>7-⑤,8-② applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Hydrocephalic shunt</td>
<td>A device used to transport excess cerebrospinal fluid from the brain to another absorption site within the body (the atrium or abdominal cavity) of a patient with hydrocephalus.</td>
<td>16244000</td>
<td>IV</td>
<td>8-② applicable</td>
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</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Applicability</td>
<td>Notes</td>
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</tr>
<tr>
<td>Ventricular neurological catheter</td>
<td>A flexible tube to be surgically inserted from the cranium and through the brain to access cerebral cavity (cerebral ventricles) filled with spinal fluid.</td>
<td>32585010</td>
<td>IV</td>
<td>7-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantable ventricular catheter</td>
<td>A semi-rigid or rigid tube designed that is usually placed permanently in order to administer a drug solution into the cerebral ventricle by connecting it to an implantable drug solution infusion pump. This device is for single-use.</td>
<td>32585020</td>
<td>IV</td>
<td>8-⑥</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter with measurement transducer</td>
<td>A flexible tube or catheter with a small pressure transducer built in at the distal end. Inserted in order to accurately measure intracranial pressure. Some types drain spinal fluid. When inserted into the cranium, its physical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.</td>
<td>70301000</td>
<td>IV</td>
<td>7-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebrospinal drain tube</td>
<td>A tubular device used to drain spinal fluid from central nervous system into the cardiovascular system or peritoneal cavity in order to adjust the volume of intracranial fluid and pressure.</td>
<td>34586004</td>
<td>IV</td>
<td>6-⑥,7-⑤,7-⑥,8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brain catheter</td>
<td>A semi-rigid tube to be inserted into the brain and drain fluid to decrease intracranial pressure. This device is for single-use.</td>
<td>34895000</td>
<td>IV</td>
<td>7-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postcraniotomy drainage kit</td>
<td>A package of sterilized tubes and other devices used to remove fluid from the brain after surgery.</td>
<td>35510000</td>
<td>IV</td>
<td>7-⑥,8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventricular drainage kit</td>
<td>A kit that containing devices including an externally installed tube attachable to a catheter for the cerebral ventricles to enable sterile drainage and measurement of spinal fluid.</td>
<td>36151000</td>
<td>IV</td>
<td>7-⑥,8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocephalic shunt auxiliary valve for prevention of excessive outflow of cerebrospinal fluid</td>
<td>An auxiliary valve that is concurrently used with a shunt to treat hydrocephalus in order to prevent excessive discharge of spinal fluid due to changes in posture.</td>
<td>70302000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocephalic shunt connector</td>
<td>An implantable device used to stabilize the connection when using a hydrocephalus shunt.</td>
<td>70303000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocephalic shunt holder</td>
<td>An implantable tool used to stabilize (fix) the hydrocephalus shunt.</td>
<td>70304000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peritoneovenous shunt</td>
<td>A plastic tube surgically implanted under the skin. Used to discharge ascitic fluid continuously from the peritoneal cavity to the superior vena cava.</td>
<td>13589000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal side exchange catheter for peritoneovenous shunt</td>
<td>A silicone rubber tube that replaces a venous side catheter of an implanted ascites shunt when it is occluded.</td>
<td>70311000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peritoneovenous shunt valve kit</td>
<td>A kit that consists of a plastic or silicone rubber valve dented tube that percutaneously returns the excessive ascitic fluid to the venae cavae, a peel away sheath introducer set, and a subcutaneous conduction tunneller.</td>
<td>70312000</td>
<td>IV</td>
<td>8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inferior vena cava filter</td>
<td>A filter placed in the inferior vena cava and used to capture the embolus such as a blood clot in order to prevent pulmonary embolism (e.g., pulmonary artery embolism).</td>
<td>70327000</td>
<td>IV</td>
<td>7-⑥,8-②</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intrathecal catheter</td>
<td>A semi-rigid or rigid tube that is usually designed to be connected to an implantable drug solution infusion pump, and placed permanently to administer a drug solution into the marrow cavity. This device is for single-use.</td>
<td>70336000</td>
<td>IV</td>
<td>8-⑥</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syringomyelia shunt tube</td>
<td>A shunt tube used to direct spinal fluid retained in the lumen of spinal cord (central canal) into the subarachnoid space.</td>
<td>70346000</td>
<td>IV</td>
<td>7-⑤</td>
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<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Type</td>
<td>Applicable Use</td>
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<tr>
<td>Programmable implantable infusion pump</td>
<td>A device to be implanted to administer narcotics, short-acting anesthetics, insulin, or antitumor agents. The dose is controlled by drug concentration or radio-frequency (RF) signals from an external programming device. The pump catheter is inserted into the epidural space of the spinal canal, marrow cavity or blood vessel.</td>
<td>35687000</td>
<td>IV</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Long-term use implantable infusion port</td>
<td>A metal or non-metal device to be implanted in a patient in order to deliver a liquid or a drug into the vascular system or other anatomical region for a long-term use. It consists of the housing, self-sealing septum and catheter junction. It can be implanted in a range of anatomical sites.</td>
<td>35911004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated long-term use implantable infusion port</td>
<td>A metal or non-metal heparin-coated device to be implanted in a patient in order to deliver a liquid or a drug into the vascular system or other anatomical region for a long-term use. It consists of the housing, self-sealing septum, catheter junction, and heparin-coated catheter. It can be implanted in a range of anatomical sites.</td>
<td>35911204</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable catheter</td>
<td>A catheter to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short- or long-term use.</td>
<td>70384000</td>
<td>IV</td>
<td>7-①,8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated implantable catheter</td>
<td>A heparin-coated catheter to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short- or long-term use.</td>
<td>70385000</td>
<td>IV</td>
<td>7-①,8-②,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable catheter with urokinase</td>
<td>A catheter with urokinase that is to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short- or long-term use.</td>
<td>70386000</td>
<td>IV</td>
<td>7-①,8-②,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable suture</td>
<td>A thread (including belt-like or tubular thread and string) made of absorbable material to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>34598000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catgut suture</td>
<td>A thread (including belt-like or tubular thread and string) made of absorbable material derived from ruminant to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>13898000</td>
<td>IV</td>
<td>7-①,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polyglycolic acid suture</td>
<td>A thread (including belt-like or tubular thread and string) made of polyglycolic acid to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>13908000</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polydioxanone suture</td>
<td>A thread (including belt-like or tubular thread and string) made of polydioxanone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>16584000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polyglyconate suture</td>
<td>A thread (including belt-like or tubular thread and string) made of polyglyconate to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>17246000</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Poliglecaprone suture</td>
<td>A thread (including belt-like or tubular thread and string) made of poliglecaprone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>70407000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
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<tr>
<td>Description</td>
<td>Material/Function</td>
<td>Code</td>
<td>Classification</td>
<td>Approval</td>
<td>Notes</td>
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<tr>
<td>Polyglycomer suture</td>
<td>A thread (including belt-like or tubular thread and string) made of polyglycomer to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>70408000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Synthetic absorbable suture</td>
<td>A thread (including belt-like or tubular thread and string but excluding biological materials) made of absorbable material to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>70409000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polyethylene/polydioxanone suture</td>
<td>A thread (including belt-like or tubular thread and string) made of polyethylene/polydioxanone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>70410000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Collagen suture</td>
<td>A thread (including belt-like or tubular thread and string) made of collagen to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.</td>
<td>13899000</td>
<td>IV</td>
<td>7-④,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable surgical tape</td>
<td>A sterilized cohesive material used to maintain organs and other internal structures. The material is biodegradable, and naturally decomposes in the body over time.</td>
<td>34046000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Brachytherapy radiation source spacer</td>
<td>A spacer used to arrange therapeutic radiation sources at the target interval. The material is the same as that of suture thread.</td>
<td>70411000</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable gastrointestinal anastomosis coupler</td>
<td>A device used to connect/traverse excess tissue of the digestive organs using a joint with 2-ring components inserted into both ends of the junction. This is made of absorbable material, and is also used endoscopically.</td>
<td>18135004</td>
<td>IV</td>
<td>7-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable vascular anastomosis coupler</td>
<td>A device used to connect the tissue of blood vessels using a joint with 2-ring components inserted into both ends of the junction. This is made of absorbable material.</td>
<td>18137004</td>
<td>IV</td>
<td>7-④,8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Vena cava clip</td>
<td>An implantable extravascular device used to prevent the passage of blood clots without stopping the blood flow by partially occluding the venae cavae.</td>
<td>34962000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intracranial aneurysm surgical clip</td>
<td>A device that, by accessing a blood vessel or another anatomic site, is used to stop blood flow in the aneurysm. A clip used in cerebral aneurysm clipping in which a clip is placed across the neck of the aneurysm or a vessel surrounding the aneurysm.</td>
<td>70421010</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cerebral arteriovenous malformation surgical clip</td>
<td>A clip (including a type of clip similar to a stapler's staple) used to isolate the arteriovenous vessels in the surgical resection of cerebral arteriovenous malformations or brain tumors.</td>
<td>70421020</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cerebral blood flow blockade clip</td>
<td>A clip used to temporarily block blood flow around the target site of cerebrovascular anastomosis.</td>
<td>70421030</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cerebral artery damage restoration sheet</td>
<td>A sheet used with cerebral aneurysm clips to achieve hemostasis by wrapping the damaged blood vessel in the event of tumor artery perforation due to a detached brain tumor.</td>
<td>70422000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable suture clip</td>
<td>A device used to close the wound or bundle the end of other tissues, and stop bleeding after resection. This is absorbable, and does not need to be removed.</td>
<td>34606010</td>
<td>IV</td>
<td>7-④,8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable implantable ligating clip</td>
<td>An absorbable, implantable device indicated for use in the conduits, blood vessels and other body tissues. It is used to prevent and stop leakage from the tissue. It may be loaded into a cartridge. Some cartridges and appliers have a built-in knife to sever the tissue. The device may be supplied pre-loaded into an applier.</td>
<td>34606020</td>
<td>IV</td>
<td>7-④,8-⑤</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Subclass</td>
<td>Applicable</td>
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<tr>
<td>Implantable aneurysm clip</td>
<td>An implantable metal device indicated for use in the arteries, veins and the heart. Used to separate an aneurysm from the remaining blood vessel.</td>
<td>34958000</td>
<td>IV</td>
<td>7-④,8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable implantable fixation tissue staple</td>
<td>A U-shaped or spiral, absorbable device used to fix the tissue or connect the tissue and devices. The device may be used for suture/anastomosis along with surgical staplers. The staples are usually made of polymer, and may be loaded into a cartridge.</td>
<td>35615004</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable suture set</td>
<td>A set that combines various devices used for suture/ligation of tissues and blood vessels. Usually, it includes an absorbable suture thread, and other devices (e.g., non-absorbable suture thread, suture needle, non-woven fabric, automatic suture device, forceps, and clips) where necessary.</td>
<td>70424000</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable surgical mesh</td>
<td>An absorbable device used to cover and support soft and hard tissue after damage or degenerative disease. In case the device is made of biodegradable materials such as polyglycolic acid it can be used as a short-term implant.</td>
<td>16048004</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable ligament prosthesis</td>
<td>An implantable device that replaces or repairs the missing or damaged ligament structures, and restores their function. This is made of absorbable prosthesis.</td>
<td>35717004</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable banded gastroplasty prosthesis</td>
<td>An absorbable device implanted in part of the stomach for reconstruction or functional recovery. This consists of a part to be implanted into a specific site.</td>
<td>36111004</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable hernia/thoracic wall/abdominal wall prosthesis</td>
<td>An absorbable device used to restore weakened or missing thoracic wall and abdominal wall or hernia. Some contain non-absorbable prosthesis.</td>
<td>70433004</td>
<td>IV</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable tissue reinforcement material</td>
<td>An absorbable material used to reinforce missing, weakened, and sutured organ/tissue. Automatic suture device may be used in conjunction. This is made of biodegradable substances such as polyglycolic acid, and glycolic acid-lactic acid polyester.</td>
<td>70434000</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable local topical hemostatic material</td>
<td>A device is made of materials to be absorbed in the body, used for local hemostasis, and indicated for surgical openings, and skin wounds or internal structures.</td>
<td>35895100</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable topical hemostatic material with collagen</td>
<td>An absorbable device made of collagen that is applied to a surgical incision, other skin wound, or an internal structure to achieve hemostasis.</td>
<td>35895200</td>
<td>IV</td>
<td>8-⑤,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable hemostasis gelatine-containing local topical hemostatic material</td>
<td>An absorbable device coated with gelatin used for local hemostasis in surgical openings, skin wounds or internal structures. Some are adhesive.</td>
<td>35895300</td>
<td>IV</td>
<td>8-⑤,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Albumin-containing adhesive</td>
<td>An albumin-containing general-purpose reagent that fixes the surface of a tissue onto the surface of another tissue or material.</td>
<td>33492204</td>
<td>IV</td>
<td>8-⑤,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aneurysmorraphy tissue adhesive</td>
<td>A substance such as glue and resin used to repair an aneurysm by adhering or closing the sac.</td>
<td>33511000</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Soft tissue adhesive</td>
<td>A biocompatible adhesive agent used to bond wounds to promote healing. It is made of acrylate or other synthetic substances.</td>
<td>34164100</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Collagen-containing soft tissue adhesive</td>
<td>A collagen-containing biocompatible adhesive agent made of acrylate or other synthetic substances used to bond wounds to promote healing.</td>
<td>34164200</td>
<td>IV</td>
<td>8-⑤,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central nervous cuff</td>
<td>A device such as silicone rubber sheath that covers the central nerve, and facilitates healing. It is used to prevent epidermal growth on scar tissue, or wrap the nerve end to prevent tumor formation.</td>
<td>33385004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>FDA Code</th>
<th>Class</th>
<th>Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorbable adhesion-prevention dressing</td>
<td>A bioabsorbable device to be surgically implanted. Used to prevent abnormal fibrous adhesion of an organ or a part of the body to another part of the body.</td>
<td>34212000</td>
<td>IV</td>
<td>7-4, applicable</td>
</tr>
<tr>
<td>Central circulatory vascular cuff</td>
<td>A sheath device used to treat varicose veins that cover blood vessels of the central circulatory system, and prevent further damage. Usually, it is made of polymeric material.</td>
<td>34234004</td>
<td>IV</td>
<td>8-2, applicable</td>
</tr>
<tr>
<td>Absorbable periodontal tissue regenerative material</td>
<td>An absorbable material applied to lesions in the oral cavity by covering, coating, or filling, to restore periodontal tissues. Some materials contain drugs.</td>
<td>70436004</td>
<td>IV</td>
<td>8-3,13, applicable</td>
</tr>
<tr>
<td>Absorbable bone regeneration material</td>
<td>An absorbable material applied to lesions by covering, coating, or filling, to restore bone tissues. Some materials are intended to have biological effects, contain drugs, or are made of biologically derived materials.</td>
<td>70437004</td>
<td>IV</td>
<td>8-3,13,14, applicable</td>
</tr>
<tr>
<td>Collagen-containing dental bone regeneration material</td>
<td>A collagen-containing material applied to lesions in the oral cavity by covering, coating, or filling, to restore bone tissues.</td>
<td>70437004</td>
<td>IV</td>
<td>8-3,14, applicable</td>
</tr>
<tr>
<td>Porcine dental follicle derivative-containing periodontal tissue regenerative material</td>
<td>A material applied to lesions in the oral cavity by covering, coating, or filling, to restore periodontal tissues. It contains ingredients derived from swine tooth germ tissue.</td>
<td>70439000</td>
<td>IV</td>
<td>8-3,14, applicable</td>
</tr>
<tr>
<td>Soft tissue injection material with collagen</td>
<td>Injectable collagen intended for soft tissue augmentation. It may be partially absorbed.</td>
<td>70440000</td>
<td>IV</td>
<td>8,8-3,14, applicable</td>
</tr>
<tr>
<td>Hyaluronic acid-containing injectable soft tissue</td>
<td>Hyaluronic acid for injection to increase the volume of soft tissues. (Part of it may be absorbed.)</td>
<td>70441000</td>
<td>IV</td>
<td>8,8-3,14, applicable</td>
</tr>
<tr>
<td>Single-use class IV surgical procedure kit</td>
<td>A pre-packaged kit that includes all devices up to Class IV, protective coating materials and drugs that are required for general procedures. This kit is for single-use.</td>
<td>33961004</td>
<td>IV</td>
<td>8-2, applicable</td>
</tr>
<tr>
<td>Human allograft tissue</td>
<td>Tissues or organs used for transplantation between individuals of the same species but with a different genotype. Some are processed before implantation. Some are sterilized.</td>
<td>35987000</td>
<td>IV</td>
<td>8-3,14, applicable</td>
</tr>
<tr>
<td>Human autograft tissue</td>
<td>Tissue grafts derived from inside or another site of the recipient's own body.</td>
<td>38745000</td>
<td>IV</td>
<td>8-3,14, applicable</td>
</tr>
<tr>
<td>Cardiac valve for mechanical artificial</td>
<td>Artificial heart valves (mechanical valve) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular disease. The types include ball valves, tilting disc valves (single leaflet), tilting disc valves (bi-leaflet), and others. The valves are made of various materials such as silicone rubber, Stellite®, Teflon®, polypropylene, and Dacron®.</td>
<td>35590010</td>
<td>IV</td>
<td>8-2, applicable</td>
</tr>
<tr>
<td>Mechanical cardiac valve with vascular prosthesis</td>
<td>A device that combines an artificial heart valve (mechanical valve) used for autologous heart valve replacement (including re-replacement) with artificial blood vessels made of artificial materials, and used for repair or replacement of a part of veins and arteries. The artificial valves are usually tilting disc valves (single leaflet) or tilting disc valves (bi-leaflet) that are used to treat acquired or congenital valvular disease. The valves are made of various materials such as silicone rubber, Stellite®, Teflon®, polypropylene, or Dacron®.</td>
<td>35590020</td>
<td>IV</td>
<td>8-2, applicable</td>
</tr>
<tr>
<td>Bovine pericardium valve</td>
<td>Artificial heart valves (bovine pericardial valves) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular diseases. They are mostly made of materials derived from bovine pericardium.</td>
<td>35591100</td>
<td>IV</td>
<td>8-3,14, applicable</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicability</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Porcine cardiac valve</td>
<td>Artificial heart valves (porcine heart valves) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular disease. They are mostly made of materials derived from porcine valves.</td>
<td>35591200</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Porcine cardiac valve with vascular prosthesis</td>
<td>A device that combines artificial heart valves (porcine heart valves) used for autogenous heart valve replacement (including re-replacement) with porcine aorta or an artificial blood vessel. Usually, it is used to treat acquired or congenital valvular disease.</td>
<td>35591300</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Annuloplasty ring</td>
<td>A rigid or flexible device to be implanted next to the mitral valve or tricuspid valve for reconstructive treatment for valvular insufficiency (valve ring).</td>
<td>35644000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Implantable cardiac pacemaker</td>
<td>A pacemaker consisting of a pulse generator, which is implanted in a surgically-created pocket under the skin, and an electrode placed inside or on the heart, connected to the pulse generator. An implantable pacing system consists of a sealed pulse generator. A pulse generator contains a battery and an electrical pulse generating circuit board: some types of pulse generator are equipped with an additional circuit to sense cardiac activity. It is also called a permanent pacemaker, a pacer, or an implantable pulse generator.</td>
<td>12913000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Cardiomyoplasty electrical stimulator</td>
<td>A stimulator to stimulate skeletal muscles (e.g., latissimus dorsi) that surround ventricles during musculoplasty performed in order to increase cardiac output. The stimulator consists of an implantable pulse generator that serves as a heart pacemaker and a neuromuscular stimulator. The pacemaker electrode is placed on cardiac muscle, and the muscle electrode simultaneously stimulates the cardiac muscle and the muscles that surround it. Many of them have such functions as heart pacing that takes over when the heart rate decreases below a set value. A musculoplasty heart stimulator is usually used for patients with ischemic or congestive cardiomyopathy.</td>
<td>18145000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Implantable biventricular pacemaker</td>
<td>An implantable pacemaker for cardiac resynchronization therapy, which has a function to electrically stimulate each left and right ventricles. The pulse generator is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit. Some are equipped with a circuit that senses cardiac activity.</td>
<td>70484009</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Implantable epicardial pacemaker electrode/lead</td>
<td>A lead insulated with non-conductive materials (excluded tip of the electrode), designed to be placed in the epicardium.</td>
<td>35039000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Implantable endocardial pacemaker electrode/lead</td>
<td>A lead insulated with non-conductive materials (excluded tip of the electrode), designed to be inserted through a vein and placed in a cardiac chamber. The device, which is placed in contact with the endocardial wall, transmits pacing pulses from the pacemaker to the myocardium. The device also transmits the electrical response of the heart to the pacemaker.</td>
<td>35223000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Transesophageal pacemaker electrode/lead</td>
<td>A flexible lead insulated with non-conductive material and used as conductor. One end is connected to an extracorporeal pacemaker, and the other end is placed in the esophagus to allow cardiac pacing.</td>
<td>36052000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Implantable pacemaker adaptor</td>
<td>A device used to adapt the connectors of an implantable defibrillator/pacemaker electrode/lead to a defibrillator/pacemaker. (Usually, this device is used in cases where the lead is not designed to be connected to a particular defibrillator/pacemaker). The adapter (including accessories) is implanted with the defibrillator/pacemaker system.</td>
<td>36102000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Implantable defibrillator/pacemaker electrode/lead</td>
<td>A flexible insulated conductor that connects the implantable cardioverter defibrillator/pacemaker and the heart to transmit signals from the heart to the implanted device, and therapeutic electrical current from defibrillator/pacemaker to the heart.</td>
<td>36241000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Intracardiac electrode</td>
<td>A conductor to be implanted in the cardiac muscle mainly for diagnosis of cardiac conduction disturbances.</td>
<td>16995000</td>
<td>IV</td>
<td>8-④</td>
</tr>
<tr>
<td>Extracorporeal pacemaker electrode wire</td>
<td>An electrode placed in the heart during and after cardiac surgery. It is connected to the extracorporeal pacemaker for temporary pacing.</td>
<td>70485100</td>
<td>IV</td>
<td>7-⑨</td>
</tr>
<tr>
<td>Heparin-coated extracorporeal pacemaker electrode wire</td>
<td>A heparin-coated electrode placed in the heart during and after cardiac surgery. It is connected to the extracorporeal pacemaker for temporary pacing.</td>
<td>70485200</td>
<td>IV</td>
<td>7-⑨,14</td>
</tr>
<tr>
<td>Collagen-containing myocardial patch</td>
<td>A collagen-containing device used for closure or repair of septal defects and injured cardiac muscle tissue. Usually, it is made of synthetic substances such as polytetrafluoroethylene or polyester. Some are made of animal-derived materials (including collagen).</td>
<td>35273200</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Central circulatory vascular prosthesis</td>
<td>A device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.</td>
<td>35281004</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Central circulatory cardiovascular patch</td>
<td>An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.</td>
<td>38572104</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Collagen-containing cardiovascular patch</td>
<td>An implantable, collagen-containing coated extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.</td>
<td>38572204</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Gelatine-containing vascular prosthesis</td>
<td>A gelatin-containing device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.</td>
<td>35093104</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Collagen-containing coated vascular prosthesis</td>
<td>A collagen-containing device using processed biological tissue as a raw material, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.</td>
<td>35093204</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Albumin-containing vascular prosthesis</td>
<td>An albumin-containing device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.</td>
<td>35093304</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Heparin-coated vascular prosthesis</td>
<td>A heparin-coated device made of processed biological tissue as a raw material, used for repairing or replacing a part of blood vessels such as the central circulatory vein and artery.</td>
<td>35093404</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Pulmonary arterial shunt</td>
<td>A small vascular graft used for bypassing a stenotic pulmonary artery.</td>
<td>17811000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Aortic stent graft</td>
<td>A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the thoracic aorta or abdominal aorta in order to maintain the patency of the aorta. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.</td>
<td>70488000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Coronary arterial stent graft</td>
<td>A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the coronary vessel in order to maintain the patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.</td>
<td>70489000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Synthetic myocardial patch</td>
<td>A device used for closure and repair of septal defects and damaged cardiac muscle tissue. It is made of polytetrafluoroethylene or polyester.</td>
<td>35273100</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Equine pericardial patch</td>
<td>A device used for closure and repair of septal defects, damaged cardiac muscle tissue, pericardium or a blood vessel opening produced during surgery. It is made of equine pericardium.</td>
<td>35273300</td>
<td>IV</td>
<td>8-②,14</td>
</tr>
<tr>
<td>Iliac stent</td>
<td>An expandable tubular device to be implanted in the common iliac artery or external iliac artery of patients with symptomatic atherosclerosis to increase blood vessel diameter.</td>
<td>44279000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Cardiovascular stent</td>
<td>A stent with a support structure expanded and placed in a cardiac vessel in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, a tubular scaffold or a tube with a Y-shaped branch.</td>
<td>34179000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Coronary stent</td>
<td>A stent with a support structure expanded and placed in a coronary vessel in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>36035004</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Cerebral artery stent</td>
<td>A stent with a support structure expanded and placed in a cerebral artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>70491000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Absorbable implantable fixation bolt</td>
<td>An absorbable device inserted in bone in order to ensure the safety of a traction device and other similar devices. It is fixed with nuts. Some are equipped with washers.</td>
<td>16077004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Reg. Category</td>
<td>Applicable Status</td>
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<td>-----------------------------------------</td>
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</tr>
<tr>
<td>Absorbable implantable fixation screw</td>
<td>An absorbable device to fix bones by applying plates or nails to the bone, fixing soft tissue to the bone, or stabilizing bone fragments. This is used for orthopedic surgery and maxillofacial surgery, etc. The screws come in various types such as cortex bone screws, cancellous bone screws, ankle bone screws, navicular bone screws, screws with a partial thread and screws where the thread occupies the entire shaft. Lag screws are used in a special way in order to compress the entire bone fragments.</td>
<td>16101004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation staple</td>
<td>A U- or other shaped absorbable device to be implanted in a fractured bone for fixation or repair in cases of orthopaedic surgical bone fracture or fracture of the mandible. It may also be used to fix ligament/tendons or other structure to the bone.</td>
<td>16103004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation nut</td>
<td>An absorbable device used with bone fixation devices such as bone screws and bone bolts to enhance fixation. It may also be used when the hole is larger than the screw diameter.</td>
<td>32847004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation pin</td>
<td>An absorbable device used to support an internal/external fixation or the traction device, to fix soft tissue and ligament onto the bone, and to stabilize bone fragments.</td>
<td>32854004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation button</td>
<td>A button-shaped absorbable device used as fixing material for joint reconstruction.</td>
<td>70497000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable vertebral body prosthesis</td>
<td>A device that is replaced or repair one or multiple vertebral bodies or spinal columns which are lost due to trauma, deformation or degenerative disease. It is made of absorbable materials.</td>
<td>34170004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation plate</td>
<td>An absorbable implantable, fixation device that is fixed to fractured bone fragments with screws in order to fill the fracture gap and protect the fractured part from stress in cases of bone deformities and treatment for bone fracture. It is also used for bone lengthening for pathologically fractured bone, as a reinforcement in cranial or maxillofacial surgery, or for fusion of joints where fixation is required.</td>
<td>35241004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation tack</td>
<td>An absorbable device for bone fixations, used to fix plates, etc. which are used for bone fracture treatment, or the like.</td>
<td>70498000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable sheet</td>
<td>An absorbable device used to cover and support the missing bone part, etc. Some have multiple holes.</td>
<td>70499000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation system</td>
<td>An absorbable device that consists of a case and multiple trays. It includes various implants and special surgical devices. This system is designed for specific surgeries for bone fracture and the spinal column, corrective surgery and ligament reconstruction. In order to maintain this system, implants are restocked after use.</td>
<td>35642004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation wire</td>
<td>An absorbable, implantable device used to fix bones. This is used for various purposes – e.g., as fastening wire that assists bone fixation; as figure-eight loop for re-joining the olecranon, tibial tubercle or greater trochanter; as reinforcement for bone screws and bone-plate fixation; as a Kirschner wire that supports the toes and fingers (joint fixation). It comes in various materials. Some are expandable to be elongated or coiled, and others are rigid.</td>
<td>35685004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable ligament fixation anchor</td>
<td>An absorbable, implantable device used to connect one or both ends of a ligament, tendon or artificial ligament onto the bone.</td>
<td>36174004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation washer</td>
<td>An absorbable device used along with bone fixation devices such as bone screws and bone bolts in order to enhance fixation or prevent soft tissue injury.</td>
<td>36198004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Regulation</td>
<td>Applicability</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Absorbable intraspinal fixation system</td>
<td>A device that consists of rods, plates, hooks, screws (including pedicle screws), connectors, wires, cables and other tools. It is used for fixation, support, or alignment correction of the spinal column. Usually, it is made of metals, polymers, or other materials that include absorbable materials. It may also be used for fracture fixation, degenerative or congenital anomalies.</td>
<td>37272004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable spinal cage</td>
<td>A device used to add, correct or repair the height of the spinal column as a substitution for a part of the intervertebral disk or spinal column. Usually, it is made of absorbable materials.</td>
<td>38161004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable bone fixation band</td>
<td>An absorbable wires, cables, and bands used to fasten/suture bone and soft tissue, fix bone to an implant, fix bone to bone etc. Usually, it is made of a polymeric material.</td>
<td>70502000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable implantable fixation cable</td>
<td>An absorbable cable (made up of stranded wire) used for bone fixation. It is used as an internal fixation device. It is used to reunite fractured bones or an osteotomy section in the olecranon, patella, medial malleolus, or greater trochanter, and to fix the spinal column, generally through the use of a fastening apparatus. It includes an implant used with cables. Usually, it is made of a polymeric material.</td>
<td>70505000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Natural bone graft</td>
<td>A bone to be transplanted from the donor to the recipient for reinforcement in plasty or reconstruction, for bone formation or for mechanical support. The bone is collected from another site of the recipient, or collected from other patients and undergone pretreatment.</td>
<td>11910000</td>
<td>IV</td>
<td>8-⑱,14</td>
</tr>
<tr>
<td>Collagen-based bone matrix implant</td>
<td>A collagen-containing material inserted or transplanted into the body to be replaced with bone lost due to trauma, osteoporosis or morbidity.</td>
<td>17756000</td>
<td>IV</td>
<td>8-⑱,14</td>
</tr>
<tr>
<td>Absorbable tendon prosthesis</td>
<td>An implantable device for replacement or repair in order to restore the function of a lost or damaged tendon. It is made of absorbable materials.</td>
<td>32869004</td>
<td>IV</td>
<td>8,8-⑤</td>
</tr>
<tr>
<td>Absorbable cement spacer</td>
<td>An absorbable device used to secure the thickness of bone cement (e.g., polymethyl methacrylate [PMMA]) between the embedded artificial joint and the bone.</td>
<td>33982004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable cement bone plug</td>
<td>An absorbable device used as closure to seal the marrow cavity to limit the passage of bone cement (used as cement restrictor). It is made of absorbable materials.</td>
<td>34031004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Absorbable tendon spacer</td>
<td>An absorbable device used to separate tissues and prevent physical contact. This prevents the tendon from adhering to adjoining tissues, and allows it to move freely.</td>
<td>35671004</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Drug-containing radial head prosthesis</td>
<td>A device used for total or partial replacement of the proximal radius (radial head). Some use bone cement for fixation while others do not. Usually, it is made of metals, ceramics, carbon, polymers or a combination of these substances are used as the raw material. It may be absorbed partially. It contains drugs.</td>
<td>35966004</td>
<td>IV</td>
<td>8,8-⑱,13</td>
</tr>
<tr>
<td>Scleral buckling device</td>
<td>An absorbable device to be inserted in the sclera in order to assist retinopexy.</td>
<td>15794000</td>
<td>IV</td>
<td>8-⑤</td>
</tr>
<tr>
<td>Implantable vagus nerve stimulator electrode/lead</td>
<td>A lead insulated with non-conductive material except for the electrode which is implanted in nerve tissue. Used to establish electrical connection between stimulator and vagus nerve.</td>
<td>44041000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Implantable myoplasty stimulator electrode/lead</td>
<td>A lead insulated with non-conductive material except for the electrode which is attached to the heart. Used to establish electrical connection between stimulator and cardiac muscle in order to assist the pumping function of the heart.</td>
<td>44044000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicability</td>
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<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Skin graft</td>
<td>A graft used to treat skin defects for the purpose of repair, reconstruction, or treatment.</td>
<td>11912100</td>
<td>IV</td>
<td>8-③</td>
</tr>
<tr>
<td>Collagen-based skin graft</td>
<td>A collagen-containing graft used to treat skin defects for the purpose of repair, reconstruction or treatment.</td>
<td>11912200</td>
<td>IV</td>
<td>8-③, 14</td>
</tr>
<tr>
<td>Intracardiac patch</td>
<td>A device made of synthetic materials to be used for reinforcement or repair of damaged membrane of the heart. It may also be used as a pledget.</td>
<td>31744000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Absorbable ENT polymer hemostat</td>
<td>An absorbable device used for soft tissue replacement or repair in the ear, nose or throat (ENT) surgery. Some are made of collagen or absorbable natural gelatin etc.</td>
<td>33310204</td>
<td>IV</td>
<td>7-④, 14</td>
</tr>
<tr>
<td>Implantable absorbable synthetic/carbon fibre tissue reconstructive prosthesis</td>
<td>A material made of polytetrafluoroethylene (PTFE) reinforced with carbon fiber to produce composite materials for absorbable implants. In cosmetic surgery, it is used to restore the structure of bones and tissues around the jaw, nose, and eye.</td>
<td>33473204</td>
<td>IV</td>
<td>8-③, 14</td>
</tr>
<tr>
<td>Meningeal prosthesis</td>
<td>A biological or artificial device used to repair meninges.</td>
<td>35614000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Nerve sheath prosthesis</td>
<td>A device used for replacement or repair to restore functionality to the nerve sheath.</td>
<td>35650000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Nipple prosthesis</td>
<td>A device to be replaced with or repair natural nipples lost or resected by surgery. Although this has the &quot;outer&quot; surface, it is considered as implant because it is embedded in tissue for connection.</td>
<td>35681000</td>
<td>IV</td>
<td>8-⑧</td>
</tr>
<tr>
<td>Implantable contraceptive drug delivery device</td>
<td>A device such as a small, hollow rubber rod. Loaded with a contraceptive agent such as the contraceptive hormone levonorgestrel, and embedded under the skin of the upper arm to steadily release the contraceptive agent into the whole body.</td>
<td>35945000</td>
<td>IV</td>
<td>8-⑥</td>
</tr>
<tr>
<td>Human dura mater graft</td>
<td>An allograft made of the cadaveric dura mater. Usually, it is processed, sterilized, and used for reconstruction or replacement of the recipient's dura mater. Since the dura mater is vital to maintain the integrity of the spinal cord, this device is efficacious when it is used to obtain the integrity of the spinal cord. It is important for the spinal cord to be constantly protected from damage and excessive pressure.</td>
<td>36036000</td>
<td>IV</td>
<td>8-②, 14</td>
</tr>
<tr>
<td>Artificial pericardial prosthesis</td>
<td>A combination device that introduces sheet prosthesis (conical dual layered fibroserous sac that wraps the heart and the root of large blood vessels) or embolization implant into the part of pericardial defect to compensate for the pericardial defect. Sheet material and embolization implants are made of biological or artificial materials. It consists of the sheet materials, embolization implant, and inserter. Some kits include other items that are necessary for surgery.</td>
<td>36182000</td>
<td>IV</td>
<td>8-②</td>
</tr>
<tr>
<td>Mammary prosthesis</td>
<td>An implantable device used for breast reconstruction or breast implantation. Expanded with sterile solution.</td>
<td>36196000</td>
<td>IV</td>
<td>8-⑧</td>
</tr>
<tr>
<td>Gel-filled mammary prosthesis</td>
<td>An implantable device used for breast reconstruction or breast implantation. The shell is fully or partially filled with silicone gel in advance, or filled during surgery.</td>
<td>36197000</td>
<td>IV</td>
<td>8-⑧</td>
</tr>
<tr>
<td>Xenograft</td>
<td>A tissue graft that is used for heterologous transplantation between different species (including humans).</td>
<td>38746000</td>
<td>IV</td>
<td>8-③, 14</td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Regulation</td>
<td>Applicable</td>
<td>Remarks</td>
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<tr>
<td>Artificial dura mater An artificial membrane used to supply or replace the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy. It is either absorbable or non-absorbable. The non-absorbable membrane may be used to prevent adhesion of the brain surface to the dura mater.</td>
<td>70510000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Synthetic artificial dura mater An artificial membrane used to supplement, or be replaced with the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy. It is either absorbable or non-absorbable. The non-absorbable membrane may be used to prevent adhesion of the brain surface to the dura mater.</td>
<td>70511000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable biventricular pacing pulse generator with defibrillation feature An implantable pulse generator mainly used to treat cardiac failure, which has a function to electrically stimulate each left and right ventricles. It is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit, and is equipped with a circuit that senses cardiac activity. The device delivers an appropriate defibrillation pulse to the cardiac muscles as necessary when tachycardia is detected so as to decrease the heart rate to the normal range, and delivers a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range.</td>
<td>70514000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable biventricular pacing pulse generator without defibrillation feature An implantable pulse generator mainly used to treat cardiac failure, which has a function to electrically stimulate each left and right ventricles. It is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit, and is equipped with a circuit that senses the cardiac activity. The device delivers a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range.</td>
<td>70515000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Circulatory assist centrifugal pump A special centrifugal pump used to maintain blood circulation in the event of cardiac failure. It assists blood circulation (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function. The dependency on artificial support is due to the absence of normal cardiac function. This is used to support the recovery of cardiac function for a short period during and after cardiotomy.</td>
<td>36379100</td>
<td>IV</td>
<td>7-⑥,8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated circulatory assist centrifugal pump A special, heparin-coated centrifugal pump used to maintain blood circulation in case of cardiac failure. It assists blood circulation (support of blood circulation in case of cardiac failure) in patients who depend on artificial support to maintain cardiac function. Dependency of artificial support is due to the lack of normal cardiac function. This is used to support the recovery of cardiac function for a short period during and after cardiotomy.</td>
<td>36379209</td>
<td>IV</td>
<td>7-⑥,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Circulatory assist spiral pump A dedicated spiral pump placed in left ventricles in order to maintain blood circulation in the event of cardiac failure. It assists blood circulation (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function. Dependency on artificial support is due to the absence of normal cardiac function (Usually, after open chest cardiac surgery).</td>
<td>36382000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Circulatory assist manually-operated crank pump A manual centrifugal pump operated by a qualified person or operator and which is used to replace an electrically powered pump when there is an outage of the main power supply. A special pump used for circulation support (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function.</td>
<td>36858000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use centrifugal pump A pump that delivers blood by using centrifugal force to assist the recovery of cardiac function for a short period during and after cardiotomy. This device is for single-use. This is used with a dedicated driving device.</td>
<td>70521100</td>
<td>IV</td>
<td>7-⑥,8-②</td>
<td>applicable</td>
</tr>
</tbody>
</table>

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<p>| <strong>Single-use heparin-coated centrifugal pump</strong> | A heparin-coated pump that delivers blood by using centrifugal force to assist the recovery of cardiac function for a short period during and after cardiotomy. This device is for single-use. This is used with a dedicated driving device. | 70521200 | IV | 7-⑥, 8-③, 14 | applicable | N/A |
| <strong>Extracorporeal assistant artificial cardiac pump</strong> | An extracorporeal auxiliary artificial heart pump. | 70522010 | IV | 7-⑥ | applicable | applicable |
| <strong>Intravascular membrane oxygenator</strong> | A type of membrane artificial lung designed to support internal gas exchange for a long-term use. | 18133000 | IV | 8-③ | applicable | — |
| <strong>Assistant artificial heart driving unit</strong> | An extracorporeal device that drives and controls an extracorporeal assistant artificial heart blood pump that supports circulation in patients with severe cardiac failure. | 70560000 | IV | 7-⑥ | applicable | applicable |
| <strong>Single-use extracorporeal assistant artificial cardiac pump</strong> | An extracorporeal auxiliary artificial heart pump. This device is for single-use. | 70522020 | IV | 7-⑥ | applicable | — |
| <strong>Automatic implantable defibrillator</strong> | A device to be implanted in the body to monitor the electrocardiogram (ECG), deliver a defibrillation pulse to the cardiac muscles when tachycardia is detected so as to decrease the heart rate to the normal range. | 35852000 | IV | 8-④ | applicable | — |
| <strong>Implantable automatic dual-chamber defibrillator</strong> | A device to be implanted in the body to monitor the electrocardiogram (ECG), deliver a defibrillation pulse to the cardiac muscles when tachycardia is detected so as to decrease the heart rate to the normal range, and deliver a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range. | 37265000 | IV | 8-④ | applicable | — |
| <strong>Fibrillator</strong> | A device that induces fibrillation by delivering a weak electrical shock. Ventricular fibrillation is caused by an MF sine wave from an electrode applied to the surface of the heart. Used for open chest cardiac surgery at normal body temperature (37°C), or treatment for arrhythmia. | 11700000 | IV | 6-⑤ | applicable | applicable |
| <strong>Implantable defibrillation electrode</strong> | A conductor used to deliver a controlled electrical shock from the defibrillator to patients so as to restore normal heart rate. A set of cables equipped with electrode is connected to the defibrillator. The internal electrode (spoon or small paddle) is directly applied to the exposed cardiac muscles (Usually, in open chest cardiac surgery). | 15033004 | IV | 6-⑤ | applicable | — |
| <strong>Artificial endocrine pancreas</strong> | A device that automatically infuses insulin, and controls blood glucose levels to treat diabetes mellitus. | 70585000 | IV | 8-⑥ | applicable | applicable |
| <strong>Implantable assistant artificial heart system</strong> | A complete ventricle bypass system that supports the left or right ventricle so as to maintain circulatory blood flow. This is implanted in the body. Usually, it is used for patients with weakening cardiac function who need support for circulation while waiting for a heart transplant. It consists of an implantable artificial heart, and extracorporeal power supply device etc. The patient may leave the hospital and stay at home while wearing the system until a suitable organ for transplantation becomes available. | 34941000 | IV | 8-③ | applicable | applicable |
| <strong>Implantable assistant artificial cardiac pump</strong> | An implantable artificial heart pump that supports the left or right ventricle so as to maintain circulatory blood flow. Usually, it is used for patients with weakening cardiac function who need support for circulation while waiting for a heart transplant. The energy is supplied from an extracorporeal power supply device. | 35266000 | IV | 8-③ | applicable | applicable |</p>
<table>
<thead>
<tr>
<th>Device Name</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Applicable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable assistant artificial heart power supply unit</td>
<td>A device that supplies electric power to an artificial heart pump. It is implanted systemically or locally along with the energy source so as to support the maintenance of appropriate circulatory blood flow.</td>
<td>37315000</td>
<td>IV</td>
<td>8-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Carotid sinus nerve electrical stimulator</td>
<td>An electric peripheral nerve stimulator that stimulates carotid artery branches (Hering's nervo) in order to decrease arterial blood pressure. Usually, the stimulator is completely implantable, and used for controlling hypertension.</td>
<td>35369000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Antiseizure brain electrical stimulator</td>
<td>A type of stimulator that stimulates a specific region of the patient's brain (e.g., cerebrum, cerebellum) in order to prevent or mitigate an attack. It is either an implantable lead/electrode system connected to the passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency wave) or a self-contained stimulator implantable at any site in the body (It has its own energy source, and has no specific dependency on external devices except for activating the stimulus and changing the settings). Used for treatment of epilepsy, spasmodic disorder, and dyskinesia (e.g., cerebral palsy).</td>
<td>36220000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Coma arousal vagus nerve electrical stimulator</td>
<td>An electrical nerve stimulator that continuously stimulates the vagus nerve to arouse the patient from vegetative state (e.g., severe coma). The stimulator consists of a pulse generator, and a lead wire connected to an electrode implanted under the skin near the left vagus nerve.</td>
<td>37310000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Psychiatric therapy vagus nerve electrical stimulator</td>
<td>An electrical brain stimulator that stimulates a specific region of the vagus nerve during psychotherapy. The stimulator usually consists of an extracorporeal pulse generator and an electrode.</td>
<td>37311000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable gait neuromuscular electrical stimulator</td>
<td>An electrical neuromuscular ambulation stimulator to be implanted in one or both legs. The stimulator usually consists of an implantable receiver with an electrode placed around the nerve and an extracorporeal transmitter that sends stimulation pulses percutaneously to the implanted receiver. The extracorporeal transmitter is usually operated by a switch located in the heel of the shoe.</td>
<td>37856000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Absorbable peritoneum catheter cuff</td>
<td>A cuff that consists of biodegradable porous material to be attached to the peritoneal dialysis catheter. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter. It helps to maintain stable contact between the skin and the catheter, and prevents bacterial invasion from the outlet.</td>
<td>70589100</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Collagen-containing peritoneum absorbable catheter cuff</td>
<td>A cuff that consists of biodegradable porous material containing collagen to be attached to the peritoneal dialysis catheter. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter. It helps to maintain stable contact between the skin and the catheter, and prevents bacterial invasion from the outlet.</td>
<td>70589200</td>
<td>IV</td>
<td>8-⑤, 14</td>
<td>applicable</td>
</tr>
<tr>
<td>Antiseizure vagus nerve electrical stimulator</td>
<td>An electrical nerve stimulator that intermittently stimulates the vagus nerve to control seizures. Usually, the stimulator consists of a pulse generator to be implanted in the anterior thoracic wall, and a lead wire connected to an electrode implanted subcutaneously near the left vagus nerve. The vagus nerve stimulator can be programmed extracorporeally after implantation. The stimulator is used to treat epilepsy by resolving seizures and reducing the frequency of seizures.</td>
<td>34210000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Technology</td>
<td>ICD-10 Code</td>
<td>Class</td>
<td>Code</td>
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<tr>
<td>Bladder/bowel evacuation neuromuscular electrical stimulator</td>
<td>A type of stimulator which is usually used to stimulate the conical end of the spinal cord (medullary cone) to induce urination and defecation. Usually, it consists of an implantable receiver equipped with an electrode (placed near the sacral nerve root), and an external transmitter (percutaneously transmits stimulation pulses to the implanted receiver). Some can induce an erection in males by adjusting the controller to stimulate a specific pair of nerve roots. Used for patients with lower body paralysis whose spinal cord is completely degenerated, and who have difficulty with urination and defecation either by voluntary reflex or by using a catheter.</td>
<td>35641000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Analgesic electrical stimulator</td>
<td>A type of stimulator that stimulates part of or the entire spinal cord for pain relief (analgesia). An implantable lead and electrode system are built in. The implantable lead and the electrode system are placed in the epidural cavity, and connected to either a passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency waves (RF) or implantable stimulator (It has its own energy source, and has no specific dependency on external devices). Used for treatment of acute or chronic refractory pain in patients for whom drug therapy is not desirable or ineffective.</td>
<td>36007000</td>
<td>IV</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable incontinence neuromuscular electrical stimulator</td>
<td>An electrical neuromuscular stimulator to treat urinary and fecal incontinence. Implanted in the abdomen with an electrode placed on the wall of urinary bladder or pelvic floor. Stimulation pulses are percutaneously transmitted from the extracorporeal transmitter to the implanted receiver.</td>
<td>36175000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Tremor brain electrical stimulator</td>
<td>A stimulator that stimulates a specific region of the deep brain (e.g., thalamus) to control tremors. The tremor-controlling brain stimulator consists of an electrode implanted in the brain by stereoecephalotomy, and a lead connected to the pulse generator. The pulse generator is usually implanted near the clavicle. The stimulator is used to control various types of tremors (tremor of patients with essential tremor, tremor associated with Parkinson's disease), and symptoms of Parkinson's disease.</td>
<td>37307000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable bladder/bowel evacuation control stimulator</td>
<td>A type of implantable stimulator – i.e., an electrical neuromuscular stimulator which is usually used to treat urinary and fecal incontinence by means such as stimulating the conical end of the spinal cord (medullary cone) to induce urination and defecation. Usually, the stimulator is implanted in the abdomen, and the electrode is placed on the wall of the urinary bladder or pelvic floor. Some can induce an erection in males by stimulating a specific pair of nerve roots. Used also for patients with lower body paralysis whose spinal cord is completely degenerated, and who have difficulty with urination and defecation either by voluntary reflex or by using a catheter.</td>
<td>70599000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable stimulator for pain relief</td>
<td>A type of implantable stimulator system that stimulates part of or the entire brain or spinal cord for pain relief (analgesia). An implantable lead and electrode are built in. They are placed in the epidural cavity or in the skull, and connected to the implantable stimulator (It has its own energy source, and has no specific dependency on external devices). Used for treatment of acute or chronic refractory pain in patients for whom drug therapy is not desirable or ineffective.</td>
<td>70600000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Pacemaker/defibrillator lead extraction kit</td>
<td>A kit that includes devices used to remove an implanted pacemaker or defibrillator lead. The devices in the kit are usually used in combination in order to remove the implanted lead. Usually, a stylet, an expansion sheath, a snare, and a collection basket are included.</td>
<td>18111000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Central circulatory remote afterloading brachytherapy therapeutic radionuclide system</td>
<td>A device that places a radiation source temporarily at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.</td>
<td>38300004</td>
<td>IV</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Central circulatory manual brachytherapy therapeutic radionuclide system</td>
<td>A device that places a radiation source manually or automatically at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device does not equip a remotely controlled radiation source transporter.</td>
<td>38299004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
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<tr>
<td>Central circulatory remote afterloading brachytherapy therapeutic radionuclide source</td>
<td>A device for the central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source used for the after-loading brachytherapy device is provided in various physical configurations – e.g., a single encapsulated radiation source (sealed radiation source), ribbon radiation source, plated, foiled, or embedded radiation source, and encapsulated liquid or gel. The radiation source is contained in a sealed storage container installed in the after-loading device, and transferred to the treatment site via guide tube in various structures.</td>
<td>38302004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Central circulatory permanent implant manual brachytherapy therapeutic radionuclide source</td>
<td>A device for the central circulatory system to be placed permanently in the body for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. Generally, it is placed in the body by an applicator under X-ray fluoroscopy or endoscopy. The radiation source, which is permanently placed manually, is designed to achieve compatibility with tissues. The radiation source can be selected from the following forms – e.g., microsphere, globe, stent, seed, and wire-in order to generate low-energy photons, beta particles, or alpha particles.</td>
<td>38303004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Central circulatory temporary placement manual brachytherapy therapeutic radionuclide source</td>
<td>A device for the central circulatory system that uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor, and is placed in the body temporarily, and removed after the predetermined treatment period. It is used for brachytherapy treatment, inserted and removed manually or under endoscopy. The radiation source, which is temporarily inserted manually, is supplied in various forms – e.g., encapsulated, sealed, plated, foiled, or embedded. The radiation sources are inserted directly in the body, or inserted using a catheter or an applicator include the following forms: a needle, globe, ovoid, seed, or wire, or liquid sealed in the cuff of a catheter.</td>
<td>38304004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Brain manual brachytherapy applicator</td>
<td>An applicator specifically designed for brain radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, placement under endoscopy, or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in the brain. Some applicators are designed in a standard configuration, and others are designed so as to handle specific radiation sources. This category includes associated devices such as brain applicator, positioner, template, and catheter guide which are used for manual administration of the radiation source in short-distance irradiation such as hollow needles, tubes, and catheters.</td>
<td>38412000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Brain remote afterloading brachytherapy applicator</td>
<td>A remote controlled brachytherapy applicator designed exclusively for brain radiotherapy for temporary implantation in the body. It serves as a computer-controlled guide for temporary placement and removal of a single or multiple therapeutic radiation sources in the brain. This category includes various applicators such as hollow needles, tubes, and catheters and associated devices and connectors.</td>
<td>38413000</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Blood vessel manual brachytherapy applicator</strong></td>
<td>A manual brachytherapy applicator designed exclusively for blood vessel radiotherapy. Most commonly, it is used to prevent formation of plaque, stenosis and restenosis in blood vessels after surgery. A single or module device designed to facilitate manual placement (placement and removal under endoscopy or using an image diagnostic system) of single or multiple therapeutic radiation sources in the treatment site. Some applicators are designed in a standard configuration, and others are designed so as to handle specific radiation sources.</td>
<td>38432000</td>
<td>IV</td>
<td>7-③,7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Blood vessel remote afterloading brachytherapy applicator</strong></td>
<td>A remote controlled brachytherapy applicator designed exclusively for radiotherapy in blood vessels. This treatment is used to prevent plaque formation, and stenosis in blood vessels after surgery. It is designed for temporary implantation in a blood vessel, and serves as a guide for computer-controlled temporary placement and removal of single or multiple therapeutic radiation sources at treatment sites. The category includes various applicators such as hollow needles, tubes, and catheters, associated devices and connectors.</td>
<td>38433000</td>
<td>IV</td>
<td>7-③,7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Central circulatory general-purpose manual brachytherapy applicator</strong></td>
<td>A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the central circulatory system. Some applicator are designed in a standard configuration, and others are designed in various physical configurations, or designed so as to be easily processed into a configuration that can handle specific radiation sources. It comes in hollow needles, tubes, catheters, ovoid, and tandem.</td>
<td>38435004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Central circulatory general-purpose remote afterloading brachytherapy applicator</strong></td>
<td>A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the central circulatory system. This category includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38436004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Brain analgesic electrical stimulator</strong></td>
<td>A type of stimulator that stimulates the brain's internal structures for pain relief. It is either an implantable lead/electrode system connected to a passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency wave [RF]) or a self-contained stimulator implantable at any site in the body (It has its own energy source, and has no specific dependency on external devices). It is used for treatment of severe chronic refractory pain for which drug therapy is not desirable or ineffective.</td>
<td>35653000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable bone fracture healing promotion electrical stimulator</strong></td>
<td>A device that electrically stimulates bone formation (osteogenesis). It is used for refractory bone fractures (the end of the fractured bone remains disunited) as an alternative therapy to bone transplantation and as adjuvant therapy for spinal fusion. This device sends a weak electric current around a bone fracture or fixed part, or develops an electromagnetic field (the effect of concomitant induced voltage). Also known as an osteogenic stimulator.</td>
<td>70615000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Phrenic nerve electrical stimulator</strong></td>
<td>A type of stimulator that provides electrical stimulation to the phrenic nerve to rhythmically contract the diaphragm and induce breathing in patients suffering from hypoventilation. It consists of an implantable receiver (placed next to the patients' phrenic nerve) with an electrode, and an external transmitter (delivering stimulation pulses to the implanted receiver via the patient's skin).</td>
<td>35652000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable analgesic peripheral nerve electrical stimulator</td>
<td>A type of stimulator that provides stimulation from electrodes placed next to the peripheral nerve. Usually, it is either an implantable lead/electrode system connected to a passive electronic circuit (energy is guided and delivered from outside the body) or a self-contained stimulator implantable at any site in the body (it has its own energy source, and has no specific dependency on external devices). It is used for treatment of severe chronic refractory pain for which drug therapy is not desirable or ineffective.</td>
<td>38474000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
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<tr>
<td>Craniotomy surgical drill</td>
<td>A perforator used to open a hole in the vault of the cranial. When the inner table is penetrated, the clutch system releases the drill bit so as to prevent the brain surface being damaged. Usually, it is used to remove skull fragments to ensure access to the brain. (See the automatic trepan).</td>
<td>44404000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Craniotomy surgical drill attachment</td>
<td>A device connected to a hand piece, or used with a motor, and connected to a drill to open a hole in the vault of the skull (calvaria). When the inner table is penetrated, the clutch system releases the drill bit to prevent the brain surface being damaged. It uses air, nitrogen, battery or electric power as a power source. It may be inserted to allow the use of a guide wire. It comes in either a micro or macro design (See the automatic trepan).</td>
<td>42981000</td>
<td>IV</td>
<td>7-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Absorbable dental bone reconstruction implant materials</td>
<td>An absorbable biomaterial used for dental treatment by filling the missing part of jaw bone and building up jaw bone (reinforcement).</td>
<td>34006004</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Endomyocardial biopsy forceps</td>
<td>A catheter that is used to collect or remove a small amount of cardiac muscle, tumor sample or other tissue for biopsy (histological/pathological diagnosis). Usually, it consists of a catheter with a set of forceps and the operation handle.</td>
<td>70937000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Spinal surgical injector</td>
<td>An injector-like manual device used to infuse orthopedic surgical (bone) cement and artificial bone etc. into a surgical site (including the spinal column). This device is for manual operation only.</td>
<td>70957000</td>
<td>IV</td>
<td>6-④,6-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Bone absorptiometer radionuclide source</td>
<td>Radioisotopes used as radiation sources of devices for osteoabsorptiometry (bone densitometry), which are produced by either an accelerator or nuclear reactor, or exist in nature. The radiation sources used in these devices are designed to deliver multiple photon radiation beams to the target sites for the purpose of collecting information about energy attenuation based on the bone density parameters obtained from the images or by calculation. The radiation sources of devices for radiation osteoabsorptiometry are provided in the physical form of a capsule or as sealed radiation. Commonly used radioisotopes include iodine-125 (I-125), americium-241 (AM-241), gadolinium-57 (Gd-57), and cobalt-57 (Co-57).</td>
<td>38315000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Radioactive compound synthesizing facilities</td>
<td>A small-scale production facility for radioactive drugs for nuclear medicine or radiopharmaceuticals used in examinations of malignant tumors, metabolic functions, etc. For instance, these facilities include one that synthesizes positron nuclide-labeled compounds that are used in PET scanning.</td>
<td>70009000</td>
<td>III</td>
<td>10-②,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Intravascular diagnostic ultrasound probe</td>
<td>An ultrasonic transducer assembly using a catheter, reusable or for single-use. It is designed to be positioned and inserted into the veins or arteries by an operator. It is water-resistant or waterproof, and sealed in a housing with sound and electrical insulation. It is also called a vascular probe or vascular transducer, and often integrated into or concurrently used with the devices that need ultrasonic guidance and ultrasonic placement, such as endoscopic devices or biopsy needles. It consists of a single or multiple transducer element array(s) (called a piezoelectric element, active element or crystal element), attenuation materials, relining materials, and matching materials.</td>
<td>37895000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Item Description</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Class</td>
<td>Applicable</td>
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<tr>
<td>Reusable vascular surgical ultrasound probe</td>
<td>A probe used in vascular surgery. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take local images during surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. This device is reusable.</td>
<td>40770003</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable temporary use intracorporeal central nervous system ultrasound probe</td>
<td>An ultrasonic probe used temporarily in central nervous system surgery. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take local images during surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. As a part of the design of transducer casing or housing assembly, the route to introduce the biopsy needle may be incorporated. This device is reusable.</td>
<td>70021000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Pathogen inactivation/reduction system</td>
<td>A system that selectively changes the pathogenic surface structures, or irreversibly modifies the pathogenic nucleic acids with radiation in order to prevent proliferation of pathogens in blood products.</td>
<td>44185000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood irradiator</td>
<td>A device that irradiates the blood and blood components with ionizing radiation sources in order to inactivate the lymphocytes. Available sources for irradiation include cesium-137. The device is used in ordinary laboratory environments, therefore, it is designed as a self-blocking unit.</td>
<td>17437000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac catheter polygraph</td>
<td>A device that is connected to a catheter inserted into the heart and examines the hemodynamics of each part of the heart. The catheter is not included.</td>
<td>70052003</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracranial pressure gauge</td>
<td>A device that measures intracranial pressure intermittently or continuously. Usually, intracranial pressure is determined when it is necessary to monitor increases in pressure postoperatively, or when measurement of intracranial pressure is important.</td>
<td>35249000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Anaesthesia depth monitor</td>
<td>A device that shows the state of consciousness of an unconscious (anesthetized) patient by detecting, processing, and displaying biological signals from the patient. The device is capable of detecting the level of sedation, unconsciousness, and awakening based on the bispectral analyses of electroencephalography (EEG) and other EEG variables. It is used during anesthetic management or cases subject to trauma.</td>
<td>41920000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated body surface electric stimulator electrode</td>
<td>A heparin–coated conductor to be applied to the body surface so that an electric current can be passed into the tissue. It may have both negative and positive electrodes.</td>
<td>34374203</td>
<td>III</td>
<td>1,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Intramuscular stimulator probe</td>
<td>An intramuscular probe specifically designed to be used with a stimulator. It is inserted into the body and probes the nerves, etc. in less invasive surgery.</td>
<td>36957003</td>
<td>III</td>
<td>7,8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>10-4</td>
<td>Applicable</td>
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<tr>
<td>Central monitor with analytic capability</td>
<td>A unit designed to collect, process, or display vital signs and other patient data from a single or multiple bedside monitoring units. The unit is designed to actuate visual or audible signals/alarms if adverse conditions are recorded. The device is usually placed in an intensive care unit, or the central patient monitoring station in a cardiology ward, to allow healthcare professionals to simultaneously monitor biological data of a number of patients. Some devices are equipped with additional functions including Holter monitoring or ST-segment monitoring. Only devices capable of detecting arrhythmia or apnea are included in this category.</td>
<td>38470003</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac arrhythmia monitoring system</td>
<td>A device consisting of units, modules, or components (e.g., a monitor, recording device, and amplifier) for the uninterrupted detection, measurement, and display of electrical activity of the heart to generate visual or audible signals or alarms when atrial arrhythmia or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, has been detected.</td>
<td>43239000</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Multiparameter monitor with critical parameters</td>
<td>A unit that collects monitoring parameters using an embedded function kit, module, or other devices to display data, by bed or by patient. The bedside unit can be connected to the central monitor; it can also be operated alone. Monitoring parameters include an electrocardiogram (ECG), blood pressure, body temperature, cardiac output, and respiratory gases; in addition, other critical parameters (supporting detection of arrhythmia or apnea; and in the case of anesthesia, determination of dose levels of a relaxant or local anaesthesia) are included.</td>
<td>33586003</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Apnoea monitor</td>
<td>A device designed to detect cessation of breathing (apnea) of a patient, and to record, process, and display the respiratory status. Some devices are capable of printing data.</td>
<td>35194003</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Apnoea alarm</td>
<td>A device that records a patient's respiratory rate, and generates alarm signals when the respiratory rate has exceeded the preset value. The device is usually used to detect the cessation of breathing (apnea) in an infant, and to generate a warning for a parent or a caregiver in a serious situation that may become life-threatening. The device utilizes a variety of methods for monitoring (e.g., a sensor pad on which an infant lies, and a sensor chest belt).</td>
<td>36319000</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiographic module with arrhythmia analysis function</td>
<td>A type of plug-in module intended to be used with a multimodal-monitor, used for the detection and recording of electrocardiogram (ECG) signals with an arrhythmia analysis function.</td>
<td>36349003</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiographic/respiratory module</td>
<td>A type of plug-in module usually intended to be used with a multimodal-monitor, used for the monitoring of electrocardiogram (ECG) signals and respiration to detect arrhythmia or apnea. Some devices have functionality that includes calculation of the frequency of respiration and frequency of obstructive respiratory events based on the measured ECG.</td>
<td>36548000</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Nerve detection module</td>
<td>A type of plug-in module, usually intended to be used with a multimodal-monitor, used for the detection of a nerve center in a certain part of the body. The device is used when performing anesthesia or the like, to aid determination of the dose of a relaxant or a local anesthetic. The device consists of a nerve stimulation device and a receiver that records nerve action potentials.</td>
<td>37246003</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Oximetry catheter</td>
<td>A special catheter to be inserted through the inguinal or cervical vein to determine oxygen saturation (venous oxygen saturation: SvO2) in the blood flowing from the heart to the lungs.</td>
<td>15200009</td>
<td>III</td>
<td>10-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Cerebral oximeter</td>
<td>A device for the continuous measurement and monitoring of oxygen saturation in the cerebral blood. The measurement and monitoring is performed with the probe placed on the head.</td>
<td>17942000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracranial pressure monitor</td>
<td>A device that gives a warning about increased intracranial pressure (ICP) with an alert sounded ideally before increased ICP can cause neurological disorders. In addition, the device performs continuous monitoring and early warning, neither of which can be performed with other diagnostic devices. Some types can record and display ICP waves on the strip chart so that the long-term tendency of ICP can be observed.</td>
<td>16763010</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracranial pressure module</td>
<td>A type of plug-in module usually intended to be used with a multimodal-monitor, used for the detection and recording of intracranial pressure (ICP).</td>
<td>16763020</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Nerve detector stimulator</td>
<td>A device that detects the nerves intermittently to monitor the relative position of the nerves to surgical devices (e.g., a scalpel). It may be used to determine the dose of a muscle relaxant or anesthetic. It consists of a neural stimulator and a receiver that records nerve signal activity.</td>
<td>35723003</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Self monitoring glucose meter</td>
<td>A device for self monitoring blood glucose or ketones. The device is dedicated for patient use at home.</td>
<td>30854000</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated intra-arterial needle</td>
<td>A thin, sharp, hollow device used for arterial puncture. Usually, it is made of metal and coated with heparin to prevent blood coagulation.</td>
<td>12747203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Insulin hypodermic syringe</td>
<td>A device consisting of a graduated cylinder and a plunger, used for subcutaneous injection of insulin.</td>
<td>35389010</td>
<td>III</td>
<td>2-①,6-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Insulin hypodermic syringe with needle</td>
<td>A device consisting of a graduated cylinder and a plunger, with an appropriate needle, used for subcutaneous injection of insulin.</td>
<td>35389020</td>
<td>III</td>
<td>2-①,6-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Spinal anaesthesia needle</td>
<td>A device with a sharp beveled tip, used for purposes that include administration of an anesthetic or analgesic into the subarachnoid space. The device is usually sterilized, and intended for single-use.</td>
<td>35212000</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Epidural injection needle</td>
<td>A device with a sharp tip, used for administration of an anesthetic or analgesic into the epidural space. The device is sometimes used to insert a catheter into the epidural space for continuous anesthetic delivery.</td>
<td>36191010</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Spinal/epidural anaesthesia needle</td>
<td>A puncture device kit for combined spinal and epidural anaesthesia, used for administration of an anesthetic or analgesic into the epidural space or subarachnoid space. The device consists of a catheter, which delivers a local anesthetic into the epidural space continuously or repeatedly, a filter, and other components. Needles for combined spinal anaesthesia administered into the subarachnoid space and epidural anesthesia has a sharp tip used for administration of an anesthetic or analgesic. The device is sometimes used to insert a catheter into the epidural space for continuous anesthetic delivery.</td>
<td>36191020</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Sterile anesthesia needle</td>
<td>A device with a hollow tube used for percutaneous nerve block. Some devices have an insulated tube, others have a terminal which is connected to an electrode, and others have sharp and hollow tube. The device is sterilized and intended for single-use.</td>
<td>70203003</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Code Number</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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<td>Heparin-coated cardiovascular/thoracic troca</td>
<td>42401203</td>
<td>III</td>
<td>6-①,14</td>
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<tr>
<td>Long-term use jejunostomy catheter</td>
<td>10731003</td>
<td>III</td>
<td>8</td>
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<tr>
<td>Long-term use enteral feeding kit</td>
<td>11677003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Long-term use enterostomy feeding tube</td>
<td>16799003</td>
<td>III</td>
<td>8</td>
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<tr>
<td>Gastrostomy tube for long-term use</td>
<td>35419003</td>
<td>III</td>
<td>8</td>
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<tr>
<td>Long-term use gastrostomy button</td>
<td>38565003</td>
<td>III</td>
<td>8</td>
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<tr>
<td>Long-term use nasogastric tube</td>
<td>14221003</td>
<td>III</td>
<td>5-④</td>
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</tr>
<tr>
<td>Long-term use esophageal tube</td>
<td>35416003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Long-term use infant enteral feeding kit</td>
<td>36044003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Long-term use biliary catheter</td>
<td>10696013</td>
<td>III</td>
<td>8</td>
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<tr>
<td>Biliary tube</td>
<td>10696023</td>
<td>III</td>
<td>7-①</td>
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<tr>
<td>Long-term use tracheal tube cuff</td>
<td>14082003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Long-term use ventilation tracheal tube</td>
<td>14085003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Long-term use jet ventilation tracheal tube</td>
<td>17935003</td>
<td>III</td>
<td>5-④</td>
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<tr>
<td>Device Description</td>
<td>Device Description</td>
<td>Code</td>
<td>Class</td>
<td>Use</td>
<td>Suitable for</td>
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</tr>
<tr>
<td>Long-term use laser-resistant ventilation tracheal tube</td>
<td>A cylindrical, hollow tube to be inserted into the trachea to secure airway patency and administer anesthetics. It is for long-term use. It cannot be broken or ignited easily by laser beams even if it is accidentally exposed to them during brain, throat or neck surgery.</td>
<td>36064003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable long-term use nasopharyngeal tracheal tube</td>
<td>A rubber or plastic tube to be inserted through a nostril into the pharynx to maintain airway patency. It is for long-term use. It may be equipped with a 15 mm connector at the tip for oxygen supplementation. This device is reusable.</td>
<td>42421000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use oropharyngeal tracheal tube</td>
<td>A curved tube made of metal or plastic, to be inserted through the oral cavity in order to maintain airway patency at the time of gas exchange or aspiration. It is for long-term use. It is useful for preventing airflow being blocked by the tongue.</td>
<td>42424003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use esophageal/tracheal double-lumen tube</td>
<td>A dual-lumen tube that enables an airway to be secured or perform artificial respiration, ventilation, etc., regardless of whether it is inserted into either the trachea or esophagus. It has two cuffs (a cuff at the proximal end of the tube is for the trachea or esophagus, and the other in the middle of the tube is for the pharynx). It may be packaged with a connector connecting to the breathing circuit or a manual resuscitator. It is for long-term use.</td>
<td>70250003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use ureteral tube stent</td>
<td>A flexible tube inserted and placed in the ureter for purposes such as drainage or irrigation. It is for long-term use.</td>
<td>34926003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Antimicrobial urological catheter</td>
<td>A flexible tube to be inserted into the urethra to access the urinary tract for introduction, drainage, etc. of fluid. It is mixed or coated with drug or material such as antibiotics to prevent urinary tract infection.</td>
<td>34096000</td>
<td>III</td>
<td>5-②,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use self-retained urological catheter</td>
<td>A flexible tube to be placed in the bladder. It is for long-term use. It has an inflatable balloon at the distal end. It is usually used for urination, hemostasis, etc.</td>
<td>34917003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use nephrostomy catheter</td>
<td>A flexible tube to be inserted percutaneously into the renal pelvis to access the upper urinary tract. It is for long-term use.</td>
<td>10735003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use nephrostomy tube</td>
<td>A tube used to perform nephrostomy from the body surface area of the pelvis to the kidney. It is for long-term use.</td>
<td>14224003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Stoma drainage urological catheter</td>
<td>A flexible tube to be inserted into a urological fistula for urination on a long-term basis.</td>
<td>31074009</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Suprapubic urological catheter</td>
<td>A flexible tube to be inserted directly into the bladder through an incision made above the pubis (above the pubic arch) in a male or female patient for urination.</td>
<td>34924003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Kidney stone filter</td>
<td>A filter to be placed in the urinary duct to prevent a renal stone from moving from the kidney into the bladder.</td>
<td>11171000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated arterial cannula</td>
<td>A semi-rigid heparin-coated tube to be inserted into an artery and utilized as a guidepath for solutions. Usually, it is inserted with a removable trocar. This device is for single-use.</td>
<td>34893203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated femoral cannula</td>
<td>A semi-rigid or rigid heparin-coated tube inserted into the femoral blood vessel and utilized as a guidepath for solutions. This device is for single-use.</td>
<td>34902203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated venous cannula</td>
<td>A semi-rigid or rigid heparin-coated tube to be inserted into a vein and utilized as a guidepath for solutions. Usually, it is inserted with a removable trocar. This device is for single-use.</td>
<td>34905203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Details</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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<tr>
<td>Catheter for drug administration angiography</td>
<td>A flexible tube designed to inject contrast media into a visceral organ or the peripheral vascular system for visualization of the vascular system in the target body site. It is also used for administration of pharmaceuticals.</td>
<td>10688103</td>
<td>III</td>
<td>6·13,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter for heparin-coated drug administration angiography</td>
<td>A flexible heparin-coated tube designed to inject contrast media into a visceral organ or the peripheral vascular system for visualization of the vascular system in the target body site. It is also used for administration of pharmaceuticals.</td>
<td>10688203</td>
<td>III</td>
<td>6·14,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug administration angiographic kit</td>
<td>A kit of devices and instruments used for preparation for radiographic visualization of the arteries in specific organs or body parts, or for administration of pharmaceuticals.</td>
<td>16545003</td>
<td>III</td>
<td>6·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated guiding intravascular catheter</td>
<td>A flexible heparin-coated tube used as a conduit to insert a balloon catheter and guide wire in percutaneous vascular surgery.</td>
<td>17846213</td>
<td>III</td>
<td>6·14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated vascular indwelling sensor</td>
<td>A heparin-coated sensor that is inserted into the peripheral blood vessel, and determines blood pressure, partial pressure in the blood, temperature, etc.</td>
<td>70273000</td>
<td>III</td>
<td>6·14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated catheter introducer</td>
<td>A heparin-coated sheath to be used in a vein or artery to facilitate percutaneous placement of a catheter.</td>
<td>10678203</td>
<td>III</td>
<td>6·14</td>
<td>applicable</td>
</tr>
<tr>
<td>Introducer catheter</td>
<td>A catheter used with a guiding catheter with a lumen of 9 Fr or wider. It is used to narrow the lumen of the guiding catheter when it is inserted, for better lubrication between the catheter and guide wire and to facilitate insertion.</td>
<td>70281000</td>
<td>III</td>
<td>6·6·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-central circulatory thrombectomy vibration catheter</td>
<td>A flexible tube that breaks up a thrombus in the blood vessel of the non-central vascular system. The device fragments the thrombus percutaneously and through the inner cavity. The tip of the catheter vibrates to make fragments small enough to be suctioned or removed.</td>
<td>70282000</td>
<td>III</td>
<td>6·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Transjugular intrahepatic portal vein access set</td>
<td>A set used to access the intrahepatic portal vein from the jugular vein percutaneously. The set contains devices for imaging of the hepatic vein, portal vein, bile duct and for liver biopsy, and a balloon catheter to dilate a shunt for performing shunting with the stent.</td>
<td>70285000</td>
<td>III</td>
<td>6·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated intravenous catheterization kit</td>
<td>A heparin-coated kit containing devices to be used for inserting a catheter through the vein.</td>
<td>12161203</td>
<td>III</td>
<td>6·14</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose vascular catheter cuff</td>
<td>A device mainly has effects on the growth of subcutaneous tissue. It is applied to the insertion site of a vascular catheter in order to support the prevention of infection.</td>
<td>17470000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Vascular catheter guidewire</td>
<td>A device used for adjusting the position of, and supporting the delivery of a catheter. It is generally made of coated or uncoated stainless steel. The coating makes it easier to move in the blood vessel.</td>
<td>35094103</td>
<td>III</td>
<td>6·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated vascular catheter guidewire</td>
<td>A device used for adjustment of positions of a catheter, a lead wire, etc. and support moving them. It is made of heparin-coated stainless steel, plastic, etc. The coating makes the wire move easily in the blood vessel and prevents thrombus formation.</td>
<td>35094203</td>
<td>III</td>
<td>6·14</td>
<td>applicable</td>
</tr>
<tr>
<td>Vascular embolization prosthesis</td>
<td>An artificial device used therapeutically for promoting thrombus formation in the vein or blocking the blood flow.</td>
<td>35449003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-central circulatory intravascular ultrasound catheter</td>
<td>A catheter that ultrasonically diagnoses the interior of the blood vessel in the non-central circulatory system. It is equipped with a transducer that sends and receives ultrasonic at the proximal end.</td>
<td>70289003</td>
<td>III</td>
<td>10·4</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Code</td>
<td>Applicable</td>
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<tr>
<td>Microcatheter</td>
<td>A catheter with a small diameter used for selection of blood vessels having a diameter of 1 to 2 mm and for treatment in highly selective angiography and embolization. The tip is equipped with a function that enhances visibility so that the position can be confirmed under fluoroscopy.</td>
<td>70296013</td>
<td>III</td>
<td>6-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic microcatheter</td>
<td>A catheter with a small diameter used for treatment in the ophthalmic therapeutic area. The tip may be equipped with a function to enhance visibility so that the position can be confirmed under fluoroscopy.</td>
<td>70296023</td>
<td>III</td>
<td>6-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter for microdialysis</td>
<td>A catheter with a small diameter having a dialysis membrane around the tip. It collects components of the body fluid from the tissues at the insertion site via dialysis fluid supplied to the lumen of the catheter.</td>
<td>70297000</td>
<td>III</td>
<td>6-3,7-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter for peripheral intravascular</td>
<td>A flexible tube inserted into the peripheral blood vessels (the peripheral vascular system) which are percutaneously accessible. It is short in length so that its distal end can be held near the insertion site. Usually, this device contains a plastic tube 2 to 8 cm long (1 to 3 inch), and a metal stylet is installed inside the lumen (catheter-over-introducer-needle). This is an injection device most commonly used for short-term placement (usually no longer than a week), for administration of nonirritating solutions, electrolytes, vitamins and drugs, and for injection of certain kinds of anesthetics to the patients having good intravenous access.</td>
<td>34920000</td>
<td>III</td>
<td>7-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Lymphangiography kit</td>
<td>A kit of devices and materials used to inject a contrast material into the lymphatic vessel for the purpose of visualization in radiography. This unit provides one or more devices as a single unit for the intended purpose of the devices.</td>
<td>35168000</td>
<td>III</td>
<td>6-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Myelography kit</td>
<td>A kit, tray or set of devices and materials used to inject contrast media into the subarachnoid space (usually, the lumbar vertebra) for the purpose of visualization of the spinal cord in radiography.</td>
<td>35199000</td>
<td>III</td>
<td>6-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter for pericardial drainage with urokinase</td>
<td>A flexible tube used to drain fluid from the periphery of the heart. It contains urokinase, a biological material.</td>
<td>10741203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug administration multi-lumen catheter</td>
<td>A flexible, dual-lumen (or multiple-lumen) tube used to inject fluid into the body cavity or drain it from the body cavity. It is also used to administer drugs. Tubes used for the central circulatory system or for the central nervous system are excluded.</td>
<td>32330203</td>
<td>III</td>
<td>5-2,7-1,13</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose suction catheter for heparin-coated</td>
<td>A flexible heparin-coated tube used for removal of fluid and evacuation of air through a natural opening of the body, surgical incision or wound site. It is usually designed to be connected to a collecting can or bottle when connected to a vacuum aspiration unit.</td>
<td>34923203</td>
<td>III</td>
<td>3,7,14</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose suction catheter with urokinase</td>
<td>A flexible tube with urokinase used for removal of fluid and evacuation of air through a natural opening of the body, surgical incision or wound site. It is usually designed to be connected to a collecting can or bottle when connected to a vacuum aspiration unit.</td>
<td>34923303</td>
<td>III</td>
<td>3,7,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated thoracic drainage tube</td>
<td>A heparin-coated single-lumen or dual-lumen straight or angular tube. It is used for removal of secretions or irrigation of the thoracic cavity after thoracic surgery or cardiac surgery.</td>
<td>11308203</td>
<td>III</td>
<td>7,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Urokinase-coated thoracic drainage tube</td>
<td>A single-lumen or dual-lumen straight or angular tube with urokinase. It is used for removal of secretions or irrigation of the thoracic cavity after thoracic surgery or cardiac surgery.</td>
<td>11308303</td>
<td>III</td>
<td>7,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated drainage tube</td>
<td>A heparin-coated plastic or metal tube used for removal of exudate or purulent substances from a cavity, wound site, or infection site.</td>
<td>14191203</td>
<td>III</td>
<td>5-2,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Classification</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Drainage tube with urokinase</td>
<td>A plastic or metal tube with urokinase used for removal of exudate or purulent substances from a cavity, wound site, or infection site.</td>
<td>14191303</td>
<td>III</td>
<td>5-2,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated wound drainage kit</td>
<td>A package containing heparin-coated devices including plastic bags or bottles and a trocar to be used for draining fluid and pus from a wound.</td>
<td>35824203</td>
<td>III</td>
<td>4-2,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Abdominal side exchange catheter for peritoneovenous shunt</td>
<td>A tube made of perforated silicone rubber with holes to be exchanged when the abdominal side of the implanted peritoneovenous shunt is occluded.</td>
<td>70310000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Abdominal side exchange catheter for pleural shunt</td>
<td>A tube made of perforated silicone rubber with holes to be exchanged when the abdominal side of the implanted pleural effusion shunt is occluded.</td>
<td>70313000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Thoracic side exchange catheter for pleural shunt</td>
<td>A tube made of perforated silicone rubber with holes to be exchanged when the thoracic side catheter of the implanted pleural shunt is occluded.</td>
<td>70314000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Pleural shunt valve</td>
<td>An implantable device with a valve, made of plastic or silicone rubber, which continuously drains excessive pleural effusion from the thoracic cavity to the abdominal cavity, placed surgically or percutaneously.</td>
<td>70315000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Hydrocephalic valve prosthesis</td>
<td>A device used for adjusting the intraventricular cerebrospinal fluid pressure.</td>
<td>35965000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Arteriovenous shunt</td>
<td>A U-shaped plastic tube to be inserted between the artery and the vein and to bypass the capillary system. It is often used for arteriovenous access in hemodialysis.</td>
<td>13586000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter for arteriovenous shunt</td>
<td>A blood access device consisting of various rigid or semi-rigid tubes. It is surgically implanted in the adjoining artery and vein, and connected externally, and forms a shunt through which blood flows continuously. This device is used for hemodialysis. The connecting part of the arterial side of the shunt to the venous side is removed when a patient is connected to a set for hemodialysis blood tube, and the part is replaced to restore the shunt after the hemodialysis is completed. This device is for single-use.</td>
<td>32121000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Haemodialysis co-axial flow catheteration kit</td>
<td>A kit of tubes and needles (coaxial flow) to be used to provide blood access for hemodialysis or other purposes. It is for long-term use.</td>
<td>33799100</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Hemodialysis co-axial flow catheteration kit with urokinase</td>
<td>A kit of tubes and needles (coaxial flow) with urokinase to be used to provide blood access for hemodialysis or other purposes. It is for long-term use.</td>
<td>33799200</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable haemodialysis catheter</td>
<td>An implantable flexible tube for short- or long-term use, designed for extracorporeal circulation of hemodialysis. It is used to withdraw and infuse blood. The blood circulates through the extracorporeal blood circulation circuit of the dialyzer, and returns to the body after loop closure. Usually, it is implanted to perform standard hemodialysis in a patient with an inadequate peripheral vascular system, or with cardiovascular disease as primary disease, for whom the use of an arteriovenous fistula is not indicated.</td>
<td>37278000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Closed loop haemodialysis catheter</td>
<td>A conduit catheter designed for extracorporeal circulation during hemodialysis.</td>
<td>42452000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated emergency blood access indwelling catheter</td>
<td>A heparin-coated catheter that is implanted in the veins including the internal jugular vein and femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy.</td>
<td>70320300</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Urokinase-coated emergency blood access indwelling catheter</td>
<td>An urokinase-coated catheter that is implanted in the veins including the internal jugular vein and femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy.</td>
<td>70320400</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
</tr>
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<td>---------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Emergency blood access indwelling catheter</td>
<td>A catheter intended to be placed in veins such as the internal jugular vein or femoral vein when urgent vascular access is required to perform extracorporeal circulation in the process of blood purification. Delivery of an infusion fluid or agent external to the circuitry that is used to remove and return blood, and measurement of venous pressure may be performed.</td>
<td>70320100</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Antibacterial emergency blood access indwelling catheter</td>
<td>An antibacterial catheter that is implanted in the veins including the internal jugular vein and the femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy. Some types have a cuff. In some types, antibacterial materials are used only for the cuff.</td>
<td>70320200</td>
<td>III</td>
<td>8,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use catheter balloon repair kit</td>
<td>A kit containing adhesives, balloons, and other items to be used for repair or replacement of balloon catheters. It is for long-term use.</td>
<td>31665003</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Urokinase-coated obturator</td>
<td>A device to be inserted into the lumen of a catheter introducer or a catheter to prevent bending and lumen occlusion during long-term placement, etc. It contains urokinase, a biological material.</td>
<td>70323203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal catheter</td>
<td>A flexible tube to be inserted into the cavity that is surrounded by a bilayer sac, which lines the abdominal wall, covering most of the viscera contained inside the wall (the peritoneum).</td>
<td>16433000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Epidural catheter</td>
<td>A semi-rigid or rigid tube usually designed to be placed in the epidural space for infusion of drugs for pain management. This device is for single-use.</td>
<td>34898000</td>
<td>III</td>
<td>6-④,7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Anaesthetic conduction catheter</td>
<td>A flexible tube to be used for continuously and repeatedly infusing local anesthetics to the wound area or the vicinity of the peripheral nerve. A flexible tube used for infusion into the epidural space may be included. It may be used in diagnosis or temporary relief of chronic pain in the extremities, pelvis, abdomen and lumbar spine.</td>
<td>35795009</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated single-use general-purpose suction tip</td>
<td>A heparin–coated device to be attached to the aspirator for adjustment and management of aspiration in surgical procedures and treatment. It is a general-purpose aspiration tip for single-use.</td>
<td>35917203</td>
<td>III</td>
<td>6,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term use thoracic catheter</td>
<td>A semi-rigid or rigid tube to be inserted into the chest (the pleural cavity) to facilitate placement of a chest tube. It is for long-term use.</td>
<td>36247003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated lacrimal fluid/passage silicone tube</td>
<td>A heparin-coated silicone tube to be inserted and placed in the canaliculus, or to dilate the lacrimal passage for treatment of epiphora resulting from lacrimal punctum obstruction, canalicular obstruction, nasolacrimal duct obstruction, etc.</td>
<td>70337203</td>
<td>III</td>
<td>5-②,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood component separation bag with filter</td>
<td>A plastic bag that is used for collecting, separating, storing, processing, transporting and administering blood and blood components, and is connected to a leukapheresis filter. It does not contain blood stock solutions.</td>
<td>70358000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Leukocyte removal blood filter</td>
<td>A filter to be inserted into a transfusion line, etc. for removal of leukocytes from blood to be infused into a patient.</td>
<td>70365000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Potassium absorption blood filter</td>
<td>A filter to be used for adsorptive removal of excessive potassium from blood to be infused into a patient.</td>
<td>70367000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Type</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Anaesthetic infusion administration set</td>
<td>A transfusion set to be used for infusing an anesthetic solution into the infusion site of a patient or a recipient of the solution. Some types provide transfusion gravitationally without using an active device. Other types provide transfusion using an infusion pump or a transfusion device. It may have a transfusion filter, a T-shaped stopcock, a connection for co-infusion, etc.</td>
<td>70375000</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Infusion pressure regulator</td>
<td>A device to adjust supply of transfusion, liquid or blood by adding pressure to the infusion bag inserted in this device. The pressure is generated mechanically, pneumatically (with pressurized air), or manually (with a hand pump).</td>
<td>13100013</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Enteral feeding infusion pump</td>
<td>A special pump designed to provide nutrition directly into the stomach of patients who are unable to maintain appropriate food intake or have no appetite.</td>
<td>13209000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose infusion pump</td>
<td>A device that facilitates accurate and constant intravenous administration of a medication or solution. The device is used to provide pressure that is higher than that for an infusion kit with a manual control clamp or a medication infusion controller. The flow rate usually ranges from 1 to 999 mL per hour, and solutions or drugs are delivered from a standard fluid bag or a bottle.</td>
<td>13215000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Syringe infusion pump</td>
<td>A device designed to be used in cases where there is a requirement for delivery of a highly accurate volume of solution at a constant rate. With the capability for a low flow rate setting and flow rate conversion, the device is suitable for uses where a small amount of highly concentrated drug is administered for a long duration in the treatment of neonates, infants, or patients in a critical condition. The device can also be used for administration of epidural anesthesia.</td>
<td>13217000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Oxytocin syringe infusion pump</td>
<td>A dedicated transfusion syringe pump for administration of oxytocin. It is calibrated in the unit specifically for this use.</td>
<td>16167000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Multichannel infusion pump</td>
<td>A device that is designed to deliver 2 or more drugs or solutions continuously or intermittently into the vein, and is capable of controlling the delivery on a channel-by-channel basis. A syringe and a bag or a bottle can be used.</td>
<td>17634000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Warming high-flow infusion pump</td>
<td>A device to be used for heating and rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries. The maximum flow rate of the device may exceed 1 liter/min.</td>
<td>17907010</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Nonprogrammable implantable infusion pump</td>
<td>A non-programmable device to be implanted for bolus administration of narcotics or therapeutic drugs for intractable pain.</td>
<td>34071000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Patient-controlled analgesic infusion pump</td>
<td>A device that delivers a prescribed amount of intravenous or epidural anesthesia/analgesic when actuated by the patient. Agents can be administered either in on-demand (bolus) mode or continuous mode.</td>
<td>35932000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable insulin infusion pump</td>
<td>A device for continuous subcutaneous insulin infusion in patients with diabetes mellitus type 1. The device can also be used for intermittent administration of insulin for the treatment of patients with insulin-independent (type 2) diabetes mellitus or gestational diabetes.</td>
<td>35983000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Syringe infusion pump control unit</td>
<td>A device designed to be used with its dedicated syringe pump to support delivery of intravenous anesthesia. The infusion volume, set in advance based on the patient's (target) body weight, height, and age, and medications to be administered, can be controlled and monitored. This technique is usually called &quot;target controlled infusion&quot; (TCI).</td>
<td>37217000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicability</td>
<td>Notes</td>
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</tr>
<tr>
<td>High-flow blood transfusion pump</td>
<td>A device to be used for rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries. The maximum flow rate of the device may exceed 1 liter/min.</td>
<td>17907020</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Active infusion pressure regulator</td>
<td>A device to adjust supply of transfusion, liquid or blood by adding pressure to the infusion bag inserted in this device. The pressure is generated mechanically, or pneumatically (with pressurized air).</td>
<td>13100023</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug infusion controller</td>
<td>A drug infusion device utilizing gravity and the height of the liquid container as the only pressure source for infusion (administration) of liquid. The device may incorporate an electronic stalagmometer.</td>
<td>11010000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter drug injection port</td>
<td>A device used as an infusion site. It is located at the luer end of a catheter or an intravenous (IV) tube. This device is also used for heparin immobilization by maintaining heparin lavage in the catheter.</td>
<td>16858000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Subcutaneous port/catheter</td>
<td>A device that can be implanted for a short or long period and consists of a metal or plastic port with a self-sealing septum. It is connected to a catheter and used to deliver drugs or other liquids to the various anatomical areas or blood vessels. It is subcutaneously implanted and can deliver drugs and liquids through a medical supply pump (for drugs and liquids), or bolus administration. A catheter is included.</td>
<td>33923100</td>
<td>III</td>
<td>7-①, 8</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated subcutaneous port/catheter</td>
<td>A heparin-coated device that can be implanted for a short or long period and consists of a metal or plastic port with a self-sealing septum. It is connected to a catheter and used to deliver drugs or other liquids to the various anatomical areas or blood vessels. It is subcutaneously implanted and can deliver drugs and liquids through a medical supply pump (for drugs and liquids), or bolus administration. A heparin-coated catheter is included.</td>
<td>33923200</td>
<td>III</td>
<td>7-①, 14</td>
<td>applicable</td>
</tr>
<tr>
<td>Short-term use implantable infusion port</td>
<td>A metal or non-metal device to be implanted in a patient in order to deliver liquid or drugs to the vascular system or other anatomical areas for short-term use. It consists of a housing, a self-sealing septum, and a catheter connection. It can be implanted in various anatomical areas.</td>
<td>35911003</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug solution injection nozzle</td>
<td>A device basically consisting of a needle tube and a needle hub for spraying, injecting and applying drug solutions to the surgical area.</td>
<td>70388000</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable insulin pen injector</td>
<td>A manual device for subcutaneous insulin injection in humans. The devices are reusable (many are pen-type devices), and each injection requires a dedicated, replaceable needle tip to be attached. The device mechanism varies depending on the purpose. A cartridge, pre-filled with insulin to be injected, is inserted in the pen, and the insulin is injected by a healthcare professional or the patient, depending on the circumstances. The device is not a subcutaneous syringe.</td>
<td>70392000</td>
<td>III</td>
<td>6-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable continuous anaesthesia unit</td>
<td>A unit that houses filters, catheters, and connectors in the assembly case for continuous anesthesia after epidural anesthesia. A needle is not included.</td>
<td>70395000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Pressurized drug injector</td>
<td>A portable pump that uses non-electric power sources such as a balloon, atmospheric pressure, or a spring to administer an agent continuously at a constant rate. Some examples of this type of devices include: those that allow selection of agent infusion rate; those equipped with an injector for patient controlled analgesia (PCA); and those designed to be connected to a PCA device.</td>
<td>12504003</td>
<td>III</td>
<td>3, 11</td>
<td>applicable</td>
</tr>
<tr>
<td>Subarachnoid/epidural anaesthesia kit</td>
<td>A kit containing a set of devices necessary for injecting anesthetics into the epidural space and the spinal subarachnoid space.</td>
<td>34842003</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Regulation</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Subarachnoid anaesthesia kit</td>
<td>34845000</td>
<td>III</td>
<td>6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion pump management unit</td>
<td>36179010</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Mobile infusion pump management unit</td>
<td>36179020</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hemostatics infusion kit</td>
<td>70397000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Epidural anaesthesia catheter</td>
<td>35795000</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heparin-coated apheresis set</td>
<td>70405000</td>
<td>III</td>
<td>11-①,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ligature wire</td>
<td>14457000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable ligating clip</td>
<td>35649000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-sterile silk suture</td>
<td>34601000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Sterile silk suture</td>
<td>13910000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polyester suture</td>
<td>13906000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polyethylene suture</td>
<td>13907000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polypropylene suture</td>
<td>13909000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Polybutester suture</td>
<td>17245000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Product Description</td>
<td>Description</td>
<td>Code</td>
<td>Tax Code</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Polytetrafluoroethylene suture</td>
<td>A polytetrafluoroethylene thread (including belt-or tube-shaped thread, and string). Intended for suturing or ligation of tissues, or securing a medical device and tissue. Needles or other accessories are also included.</td>
<td>17467000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Plastic suture</td>
<td>Plastic thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>34602000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Polyamide suture</td>
<td>Polyamide thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>38847000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Polyvinylidene fluoride suture</td>
<td>Polyvinylidene fluoride thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>38873000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Polyurethane suture</td>
<td>Polyurethane thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>70412000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Vinlylidene fluoride/hexafluoropropene copolymer suture</td>
<td>Poly (hexafluoropropylene-vdf) thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>70413000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Stainless steel suture</td>
<td>Stainless steel thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>35383000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Urinary incontinence treatment tape</td>
<td>A tape made of a synthetic material used to raise the midurethra for treatment of urinary incontinence.</td>
<td>70414000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Titanium suture</td>
<td>Titanium thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.</td>
<td>70415000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Injection needle type suture unit</td>
<td>A sterile device with a non-absorbable suture that is built into a needle-like device. It is used to repair skin damage or muscle lacerations. After removal of the needle inserted into the wound site with the suture left in situ, ligation is performed. This device is for single-use.</td>
<td>70416000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable vascular anastomosis coupler</td>
<td>A device used to connect the tissue of blood vessels using a joint with components inserted into the ends of the junction. This is made of non-absorbable materials.</td>
<td>18137003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable vascular clip</td>
<td>An implantable device designed to block the blood flow in small vessels by compression.</td>
<td>35640003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive fallopian tube clip/band</td>
<td>An implantable device applied to the fallopian tubes, and used to ligate them to prevent an ovum from passing through. Usually, it is used in tubal ligation, and considered a contraceptive device.</td>
<td>33598000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive vas deferens clip/band</td>
<td>An implantable device, usually a minute clamp made of plastic placed in the vas deferens to stop the flow of sperm permanently. It is used for male sterilization instead of vasectomy.</td>
<td>42927000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-biodegradable tissue fixation staple</td>
<td>A U-shaped or spiral, non-absorbable device used for fixation of the tissues or fixation between the tissue and device. It may be used for suture, anastomosis, etc. with a surgical stapler. Usually, it is made of polymer, and may be loaded into a cartridge.</td>
<td>35615003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable suture set</td>
<td>A set combining various devices used for suture and anastomosis of tissues and blood vessels. Usually the set contains non-absorbable surgical sutures, and other devices (e.g., suture needles, nonwoven fabrics, an automatic suture device, forceps, clips) are included, where necessary.</td>
<td>70425000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable suture retention device</td>
<td>An implantable device such as a fixed bridge, a surgical button, a thread holder. It is used to support wound healing by distributing the tension of the suture more widely. The distribution of the tension of the suture helps to prevent the suture from cutting the skin or the tissue.</td>
<td>70426000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Hydrogel wound dressing for secondary healing</td>
<td>Secondary healing wound care dressings, made of hydrophilic-polymer, used to absorb exudate, reduce bleeding or body-fluid loss, and protect wounds from scraping, friction, drying, and contamination.</td>
<td>34082003</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Secondary healing saline solution-containing dressing</td>
<td>Secondary wound care dressings saturated with saline solution, intended to promote biological cleaning and the autolytic debridement process in wounds.</td>
<td>37298003</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Secondary healing hydrophilic gel-forming dressing</td>
<td>A secondary wound care dressings, usually in sheet or ribbon form, made of hydrophilic fiber, chitin, or alginate (salt and acid) or the like, which absorbs exudate and maintains a moist environment, aiding autolytic debridement.</td>
<td>43186003</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Antimicrobial dressing</td>
<td>A sterile fabric or narrow slip impregnated with an infectant and an antibacterial agent used for dressing wounds.</td>
<td>34614000</td>
<td>III</td>
<td>4·1,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Puncture protection patch</td>
<td>A patch impregnated with antimicrobials. It is used to protect the skin puncture site to suppress bleeding, absorb fluid, and protect from contamination. The antimicrobials are used to prevent microbial growth in the patch.</td>
<td>70432000</td>
<td>III</td>
<td>4,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Absorbable gauze</td>
<td>Sterile, light gauze made of oxidized cellulose, with a loose weave. It is used during surgery and absorbed into the body.</td>
<td>32376000</td>
<td>III</td>
<td>6·3</td>
<td>applicable</td>
</tr>
<tr>
<td>Absorbable dressing</td>
<td>A wound dressing and a protective dressing made of a bioengineered material. It protects wounds and is absorbed into the skin as they heal.</td>
<td>34615100</td>
<td>III</td>
<td>4·1,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Collagen-containing absorbable dressing</td>
<td>A wound dressing and a protective dressing made of a bioengineered material. It contains collagen, protects wounds and is absorbed into the skin as they heal.</td>
<td>34615200</td>
<td>III</td>
<td>4·1,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Foam wound dressing for secondary healing</td>
<td>A secondary healing wound care dressings, made of hydrophilic foam, a superabsorbent pad, intended to cover wounds with a high volume of exudate.</td>
<td>11323003</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Skin graft/donor-site dressing</td>
<td>Non-absorbable, non-adherent sheet made of mylar or other materials to dress or protect burns and various wounds including a skin graft and skin donor sites.</td>
<td>15319000</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Wound dressing kit</td>
<td>A kit, tray, or set of pre-packaged various devices, wound dressings and protective dressings, drugs, etc. necessary for dressing wounds.</td>
<td>34059000</td>
<td>III</td>
<td>4·1</td>
<td>applicable</td>
</tr>
<tr>
<td>Interactive wound dressing</td>
<td>A sterile wound dressing and a protective dressing of a synthetic or natural material. It is used to actively promote healing of wounds or burns by interacting directly and indirectly with the body tissues.</td>
<td>34083000</td>
<td>III</td>
<td>4·1,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td></td>
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<tr>
<td>Deep-cavity wound dressing</td>
<td>A wound dressing and a protective dressing made of a natural or synthetic material. It is used for management of deep wounds involving muscle or bone.</td>
<td>36226000</td>
<td>III</td>
<td>4-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Heated occlusive dressing</td>
<td>A wound dressing and a protective dressing to seal wounds to prevent exposure to the air and bacteria in the environment. This is heated to promote healing of wounds.</td>
<td>37275000</td>
<td>III</td>
<td>4-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgical mesh</td>
<td>A non-absorbable device to be used for dressing and supporting of the soft tissues or the hard tissues after damaged or onset of degenerative disease. It may be made of metal, or a polymeric material.</td>
<td>16048003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable ligament prosthesis</td>
<td>An implantable device used for replacement or repair in order to restore the function of a deficient or damaged ligamentous structure. It is made of a non-absorbable material.</td>
<td>35717003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable banded gastroplasty prosthesis</td>
<td>A non-absorbable device implanted in part of the stomach for reconstruction or functional recovery. This consists of a part to be implanted into a specific site.</td>
<td>36111003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable hernia/thoracic wall/abdominal wall prosthesis</td>
<td>A device made of a non-absorbable, synthetic fiber used for repairing a weakened or deficient chest wall, abdominal wall or a hernia.</td>
<td>70433013</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable antimicrobial hernia/thoracic wall/abdominal wall prosthesis</td>
<td>A device made of a non-absorbable, synthetic fiber used for repairing a weakened or deficient chest wall, abdominal wall or a hernia. It contains substances with antibacterial properties.</td>
<td>70433023</td>
<td>III</td>
<td>8,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable staple line reinforcement prosthesis</td>
<td>Materials made of non-absorbable synthetics including polytetrafluoroethylene. They are used to reinforce tissue defects, suture sites or junctions in combination with an automatic suture device.</td>
<td>70435000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Endocapsular ring</td>
<td>An annular band used to reinforce the mechanical safety of subluxation of the lens capsule when the zonular is weak or absent. The device is implanted in the lens capsule, generates tension and keeps the lens capsule stretched.</td>
<td>42839000</td>
<td>III</td>
<td>5-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Collagen-containing burn dressing</td>
<td>A wide layered gauze pad used to dress and protect burned skin, and absorb exudates from the burns. It contains collagen.</td>
<td>11322003</td>
<td>III</td>
<td>4,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Symblepharon ring</td>
<td>A device used to prevent the eyelid from adhering to the eyeball. For instance, it may be used to keep the wound surfaces separated in a patient with glaucoma. It may be made of a polymeric material, or a simple mucosal graft may be used.</td>
<td>16073000</td>
<td>III</td>
<td>5-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic clip</td>
<td>An ophthalmic clasp permanently or temporarily implanted to promote healing or prevent bleeding from the ocular small vessel. Malleable metals including tantalum may be used.</td>
<td>32814000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Nerve cuff</td>
<td>A device such as a silicone rubber sheath used to encase the nerve, and promote repair of the encased nerve. It is used to cover the end of the nerve to prevent tumor formation as well as epidermal growth in the scar tissue.</td>
<td>33385003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable vascular cuff</td>
<td>A sheath device that covers the blood vessel in order to prevent further damage in treatment for varicose, etc. Usually, it is made of polymeric materials.</td>
<td>34234003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Eye muscle sleeve</td>
<td>A device made of synthetic materials to be used for encasing or separating the eye muscles.</td>
<td>35669000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Lacrimal punctum plug</td>
<td>A device to be inserted into the opening of the punctum to prevent lacrimation. For instance, it may be used in patients with dry eyes.</td>
<td>36237100</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Code</td>
<td>Status</td>
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<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Collagen-containing lacrimal punctum plug</td>
<td>A collagen-containing device, inserted into the opening of the punctum to prevent lacrimation. For instance, it may be used in patients with dry eyes.</td>
<td>36237200</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable periodontal tissue regenerative material</td>
<td>A non-absorbable material to be applied to the affected area in the oral cavity by covering, application, filling, etc. for the purpose of periodontal tissue regeneration. It may contain drugs.</td>
<td>70436003</td>
<td>III</td>
<td>8,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-absorbable bone regeneration material</td>
<td>A non-absorbable material to be applied to the affected area by covering, application, filling, etc. for the purpose of bone tissue regeneration. Absorbable materials or those intended to produce biological effects are excluded. It may contain drugs, or use a biological material.</td>
<td>70437103</td>
<td>III</td>
<td>8,13,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Extra-ocular orbital implant</td>
<td>A device made of synthetic materials to be used for compressing the eyeball where retinal detachment is caused by injuries, etc.</td>
<td>70442000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Dermal dilator</td>
<td>A device to be temporarily implanted subcutaneously to dilate the surrounding skin. Usually, a balloon is implanted subcutaneously where solutions including saline solution are infused.</td>
<td>70443003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Hydrophilic-bead dressing</td>
<td>A bead made of porous spherical polymer, such as a dextranomer bead, in which sugar chains have a network structure cross-linked with epichlorohydrin, a cross-linking agent. It is applied to skin defects with exudates in leg ulcers or severe burns to promote granulation.</td>
<td>33616000</td>
<td>III</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Gastroplasty band</td>
<td>A belt or strip placed around the upper stomach (inside the body) to form a small sac with a narrow outlet in order to reduce food intake for weight loss. It may be surgically placed, or adjustable.</td>
<td>17649000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use class III surgical procedure kit</td>
<td>A kit containing all items (Class I to Class III) necessary for general surgical treatment, including various devices, dressings, and drugs. This kit is for single-use.</td>
<td>33961003</td>
<td>III</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal irrigation kit</td>
<td>A package containing syringes and other devices for the peritoneal lavage.</td>
<td>12996009</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Invasive external cardiac pacemaker</td>
<td>A device that generates pacing impulses from an external pulse generator through an electrode inserted into the heart from the major vein (e.g., subclavian electrode), or by contacting directly with the heart wall. An external temporary pacemaker is used to generate electrical impulses to the heart when sinus node (SA node) abnormalities or cardiac conduction abnormalities occur.</td>
<td>35224000</td>
<td>III</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Noninvasive external cardiac pacemaker</td>
<td>A device that generates electrical impulses to stimulate the entire heart for resuscitation, treatment for arrhythmias, or temporary pacing during invasive procedures possibly causing cardiac arrhythmia or ventricular asystole (cardiac arrest) in contrast to invasive, single chamber, or dual chamber pacing. The pulses from this device are usually applied to the chest surface via an electrode. However, the device may be connected to an implanted lead.</td>
<td>35822000</td>
<td>III</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Transesophageal external cardiac pacemaker</td>
<td>A non-invasive device to provide electrical impulses (pacing stimulation) that stimulate the entire heart through one or more electrode(s) placed in the esophagus. It is for temporary use.</td>
<td>36046000</td>
<td>III</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Pacemaker programmer</td>
<td>A device to be used to change one or more electrical operating characteristics non-invasively. The programmer can read out parameters stored in the pacemaker and provide information about the patient status.</td>
<td>15993000</td>
<td>III</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable pacemaker bag</strong></td>
<td>An implantable device to be used to fix a pacemaker. This is intended to provide a stable environment for pacemaker implantation. Usually, it is made of polymer mesh.</td>
<td>16038000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Pacemaker electrode analyzer</strong></td>
<td>A device that is connected to an implanted pacemaker lead, and provides variable pacing pulses to determine the pacing threshold and voltage of cardiac R waves, etc. in a patient.</td>
<td>31699000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Pacemaker charger</strong></td>
<td>A device to be percutaneously used to recharge the battery of a rechargeable pacemaker.</td>
<td>33658000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-central circulatory vascular prosthesis</strong></td>
<td>A device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.</td>
<td>35281003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-central circulatory cardiovascular patch</strong></td>
<td>An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the non-central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.</td>
<td>38572103</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Collagen-containing non-central circulatory cardiovascular patch</strong></td>
<td>An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the non-central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene. A device impregnated with biological substances such as collagen is included.</td>
<td>38572203</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated temporary use indwelling vascular prosthesis</strong></td>
<td>A heparin-coated device made of synthetic resin. It is used for the temporary bypass of blood from vessels including veins and arteries.</td>
<td>70487103</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Gelatine-containing non-central circulatory vascular prosthesis</strong></td>
<td>A gelatin-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.</td>
<td>35093103</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Collagen-containing non-central circulatory vascular prosthesis</strong></td>
<td>A collagen-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.</td>
<td>35093203</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Albumin-containing non-central circulatory vascular prosthesis</strong></td>
<td>An albumin–coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.</td>
<td>35093303</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vascular prosthesis with heparin for non-central circulatory system</strong></td>
<td>A heparin-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.</td>
<td>35093403</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Blood vessel stent graft</strong></td>
<td>A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the peripheral blood vessel in order to maintain the vascular patency. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is deflated and removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.</td>
<td>70487000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Stent Type</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Certification</td>
<td>Applicable</td>
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<tr>
<td>Biliary stent</td>
<td>A stent with supporting structures, designed to be placed into the bile duct to maintain its patency. The stent can be delivered to the blocked area of the bile duct by the delivery system. Stents support the bile duct, for example by self-expanding properties, or by inflation of a balloon catheter to expand the stent. After deflating and removing the balloon catheter, just the stent stays in place. Stents are made of materials including stainless steel or resin. The stent may be a tube with a certain length, or have a tube-like scaffold structure.</td>
<td>17672000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Bronchial stent</td>
<td>A stent with a support structure expanded and placed in the bronchus in order to maintain the patency of the bronchus. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the blood vessel. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>17957000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Hand tendon prosthesis</td>
<td>An implantable device used to reconstruct the flexor tendon of the hand surgically. It is implanted and left for 2 to 6 months to help the new tendon sheath to grow. It is made of silicone elastomer or medical, polyester-reinforced, silicone elastomer.</td>
<td>35276000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ureteral stent</td>
<td>A stent with a support structure expanded and placed in the ureter in order to maintain the patency of the urethra. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>35645000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Vaginal stent</td>
<td>A stent with a support structure expanded and placed in the vagina in order to maintain the patency of the vagina. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>35646000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Tracheal stent</td>
<td>A stent with a support structure expanded and placed in the trachea in order to maintain the patency of the trachea. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>36029000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Vascular stent</td>
<td>A stent with a support structure expanded and placed the blood vessel excluding the coronary vessel and the iliac artery in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>36035003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Pancreatic stent</strong></td>
<td>A stent with supporting structures, designed to be placed into the pancreatic duct to maintain its patency. The stent can be delivered to the blocked area of the bile duct by the delivery system. Stents support the pancreatic duct, for example by inflating a balloon catheter to expand the stent. After deflating and removing the balloon catheter, just the stent stays in place. Stents are made of materials including stainless steel or resin. The stent may be a tube with a certain length, or have a tube-like scaffold structure.</td>
<td>36143000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Urethral stent</strong></td>
<td>A stent with a support structure expanded and placed in the urethra in order to maintain the patency of the urethra. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>36211000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Stent for esophageal</strong></td>
<td>A stent with a support structure expanded and placed in the lumen. This is used to treat esophageal atresia or gastroesophageal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>36227000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Colorectal stent</strong></td>
<td>A stent with a support structure expanded and placed in the lumen of the large intestine. This is used to treat colonic atresia or colorectal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>70493000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Gastroduodenal stent</strong></td>
<td>A stent with a support structure expanded and placed in the duodenal lumen. This is used to treat duodenal atresia or gastroduodenal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>70494000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hemi hip prosthesis</strong></td>
<td>A prosthetic joint used in femoral head or neck replacement. The device is used for patients with conditions including proximal hip fracture and arthritis. The device may comprise an integral component, or consist of a stem equipped with a trunnion and the femoral head. The femoral head component (the ball-shaped piece of bone) is either composed of a single piece, or formed from an outer shell, inner liner, and other parts. The devices are made of materials including metal, carbon, polymer or ceramic. There are different types of fixation: with cement and cementless.</td>
<td>33704000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Resurfacing hip prosthesis</strong></td>
<td>A prosthetic joint used for resurfacing the joint surfaces of the femoral head and acetabulum. The devices are made of materials including metals, polymer, carbon, and ceramic. Some types of device have an insertion part in the femoral component.</td>
<td>33717000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hip prosthesis acetabular component</strong></td>
<td>A prosthetic hip joint used for replacement or repair of the acetabulum. The device may be composed of an integral component, or consist of an outer shell made of metal, ceramic, or other material, and an inner liner made of metal, polymer, ceramic, or other material. Some types of device have screws or other parts to reinforce fixation within the body. There are constrained and unconstrained types.</td>
<td>35661000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Femoral component for hip prosthesis</strong></td>
<td>A prosthetic hip component used for femoral head replacement. Some devices are used for replacement of the femoral neck. The device is usually equipped with a trunnion or a femoral head at the proximal end. The device is usually made of metals, carbon, or ceramic, and composed of many parts. Some types of device have screws or other parts to reinforce fixation within the body. There are constrained and unconstrained types. There are different types of fixation: with cement and cementless.</td>
<td>35666000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Total hip prosthesis</strong></td>
<td>A prosthetic joint for replacement of the joint part of the hip joint. The device usually consists of components that fit into the femur and acetabulum. Some devices are equipped with screws, bolts, blocks, or other parts depending on the prosthetic hip joint designs. The device is usually made of metals, polymer or ceramic. When implanting components, cement may be or may not be used.</td>
<td>36315000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Unicondylar knee prosthesis</strong></td>
<td>Prosthetic joints used for replacement of one of the femoral condyles and the supporting surface of the corresponding tibial condyle.</td>
<td>32833000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Tibial resurfacing knee prosthesis</strong></td>
<td>A prosthetic joint used for replacement of the surface and missing bone at the proximal end of the tibia. The device is designed to form a joint, with the femoral condyle alone. It is generally known as an amphiarthrosis or a prosthetic tibial plateau.</td>
<td>32836000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Total knee prosthesis</strong></td>
<td>A prosthetic joint used for replacement of the entire joint surfaces of a damaged/degenerating knee joint. There are constrained, semi-constrained, and unconstrained types. Some types of device consist of parts, which are designed to be connected to each other by a hinge to form a joint. The device is usually made of metal, carbon, ceramic, polymers, or other materials; and any or all of such materials are used in the components. There are different types of fixation: with cement and cementless.</td>
<td>35667000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Knee prosthesis femoral component</strong></td>
<td>A prosthetic joint component used for repair or replacement of the femoral part of the knee joint. The device is designed to form a joint with the tibial component, and to form a joint with the prosthetic patellar component as needed. The device is usually made of metal, ceramic, or polymer, fixed with bone cement. Some types of device are equipped with a stem or a fixation mechanism.</td>
<td>35668000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Knee prosthesis tibial component</strong></td>
<td>A prosthetic joint component used for repair or replacement of the tibial plateau of the knee joint. The device is designed to form a joint with a prosthetic femoral component. The device is usually made of metal, ceramic, or polymer, fixed with bone cement. Some types of device comprise a stem, fixation screws, and a metal tray with polymer insert.</td>
<td>35669000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Knee prosthesis patellar component</strong></td>
<td>A prosthetic joint component used for patellar replacement. The device is designed to form a joint with the distal end of the prosthetic femoral component, and bone cement is used in some types of such devices. The device is usually made of materials including metal, ceramic, polymer, and carbon.</td>
<td>35679000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Classification</td>
<td>CE Marking</td>
<td>Applicability</td>
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</tr>
<tr>
<td>Shoulder prosthesis humeral component</td>
<td>A component of an artificial shoulder joint. It is attached to the proximal humerus for replacement, or repair of the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement fixation type or cement-less type is available.</td>
<td>32835000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Total shoulder prosthesis</td>
<td>An artificial joint used to reinforce or replace the joint surface of the shoulder. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. It is unconstrained, constrained or semi-constrained. A cement fixation type or cement-less type is available.</td>
<td>35670000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Shoulder prosthesis glenoid component</td>
<td>A component of an artificial shoulder joint. It is attached to the glenoid for replacement, or repair of the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement fixation type or cement-less type is available.</td>
<td>36259000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Elbow prosthesis radial component</td>
<td>An artificial joint made of metal, polymer, etc. to reinforce or replace the joint surface of the proximal radius. It may be a portion of a constrained or unconstrained artificial joint.</td>
<td>33701000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Elbow prosthesis humeral component</td>
<td>A humeral component made of metal, polymer, ceramic, etc. It is used to reinforce or replace a portion of or the entire distal humeral joint surface. A cement fixation type or cement-less type is available. It may be a portion of a constrained or unconstrained artificial joint.</td>
<td>35664000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Elbow prosthesis ulnar component</td>
<td>An ulnar component device made of metal, polymeric materials, etc. It is used to reinforce or replace a portion of or the entire proximal ulnar joint surface. A cement fixation type or cement-less type is available. It may be a portion of a constrained or unconstrained artificial joint.</td>
<td>70495000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Total elbow prosthesis</td>
<td>An artificial joint used to replace or substitute the entire surface of a damaged or deformed elbow joint. Constrained, semi-constrained, or non-constrained types are available. Some types consist of multiple parts connected by hinges and designed to form the joint in combination. Usually, it is made of metal, ceramic, carbon, polymer (the parts are made of either or all of these materials), or of a combination of these materials. A cement or cementless fixation type is available.</td>
<td>70496000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Artificial bone matrix implant</td>
<td>A device made of synthetic bone matrix to be inserted or placed inside the body to replace a bone defect caused by morbid conditions including injury or osteoporosis. Powder, liquid or paste types are included.</td>
<td>17751000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation bolt</td>
<td>A non-biodegradable device to be inserted in bone to improve safety of a traction device or a similar device. The device uses a nut for fixation: some devices are equipped with washers. The device may be made of metal or polymer.</td>
<td>16077003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation screw</td>
<td>A non-absorbable bone fixation device used to fix a plate or a nail onto bone, fix soft tissues, a sheet or non woven fiber onto bone, or stabilize fractured bone fragments. The device is used for orthopedic and maxillofacial surgery, etc. The screws come in various types such as cortical bone screws, cancellous bone screws, ankle bone screws, or navicular bone screws, with a partial or fully threaded. Lag screws are used for special case in order to compresses all of the fracture fragments. The device is usually made of metal, etc.</td>
<td>16101003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation staple</td>
<td>A non-absorbable device, including a U-shaped type, to be implanted in a fractured bone for fixation or repair of an orthopedic fracture, mandibular fracture, etc. This is also used for connecting a ligament, tendon, etc. to the bone to be fixed. Usually, it is made of metal.</td>
<td>16103003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation nut</td>
<td>A non-biodegradable device that is to be used with bone fixation devices such as bone screws and bolts, to enhance fixation. The device may be used when the bone hole is larger than the screw diameter.</td>
<td>32847003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation pin</td>
<td>A non-absorbable device used for internal/external fixation, a support of traction device, or fixation of bone, soft tissues, and ligaments onto bone.</td>
<td>32854003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable femur intramedullary fixation nail</td>
<td>A rod made of metal or other material. The device is inserted into the femoral medullary cavity, serving as a fixation device that keeps both ends of fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. The device is equipped with many components; and some devices are of the locking-type which improves fixation of bone fragments both proximally and distally; some are of the non-locking-type.</td>
<td>33187000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation compression hip plate</td>
<td>A device used for fixation of the head of the femur, fractured at its proximal end. The device usually consists of a plate, and is designed to be used with a partially threaded, large screw that is inserted into the guide hole located in the proximal end of the plate. The device is fixed to the femur using cortex bone screws.</td>
<td>34003000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Spine disc prosthesis</td>
<td>A device used to replace or repair the plate-like structure between two movable vertebral bodies. Usually, it is made from metal, polymer, other artificial materials or biological materials, or a combination of these materials.</td>
<td>34163000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Artificial vertebral body</td>
<td>A device used to replace or repair one or more defects of the vertebral body or the spine caused by injury, deformation or degenerative disease. Usually, it is made of metal, polymer, other artificial materials or a combination of these materials.</td>
<td>34170003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Rib prosthesis</td>
<td>A device used to replace or repair the entire rib or a portion of it. Usually, it is made of metal, polymer, other artificial or biological materials, or a combination of these materials.</td>
<td>34219000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation plate</td>
<td>A non-absorbable implantable fixation device that is fixed to fractured fragments with screws or the like, in order to fill the fracture gap and protect the fractured part from stress in cases of bone deformities and treatment for bone fracture. It is also used for bone lengthening for pathologically fractured bone, as a reinforcement in cranial or maxillofacial surgery, or for fusion of joints where fixation is required. The bone plate is usually made of metals and carbon, etc.</td>
<td>35241003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable fixation system</td>
<td>A non-absorbable device consisting of a container and multiple trays. There are many implants and dedicated surgical devices. This system is designed for specific operations including fracture surgery, spinal surgery, corrective surgery or ligament reconstruction. To maintain this system, any implant that has been used needs to be replenished.</td>
<td>35642003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Clamp for cranial fixation</td>
<td>A non-absorbable, implantable fixation device for cranial closure after craniotomy, or to clamp cranial fragments together for fixation in order to restore dislocation after complicated fracture of skull. Plates, discs, and auxiliary pins, etc. are used for fixation. Usually, it is made of metal, stainless steel, titanium, etc.</td>
<td>70500000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Extrasmatic fixation system</strong></td>
<td>A device that consists of a container or multiple trays. There are many implants (e.g., pins, screws, wires) and dedicated surgical devices. This system is designed for specific surgery including fracture surgery, spinal surgery, or corrective surgery. To maintain this system, any implant that has been used needs to be replenished. The external fixator can be reused by following the instructions.</td>
<td>35647003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable fixation wire</strong></td>
<td>A non-absorbable, implantable device used for bone fixation. It is used for various purposes. For instance, it is used as a fastening wire that supports bone fixation, an 8-shaped loop that reattaches the olecranon, the tibial tubercle, the greater trochanter, etc., a Kirschner wire that reinforces the toe or the finger (joint fixation) for reinforcement of bone screw fixation and bone plate fixation. Usually, it is made of metal. Some types are made of malleable materials that are elongated, or formed into a coil shape. Other types are made of inflexible and rigid materials.</td>
<td>35685003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Temporomandibular joint prosthesis</strong></td>
<td>An implantable, artificial joint used for reconstruction of the temporomandibular joint. Usually, it is made of artificial materials including metal and polymer.</td>
<td>35943000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ligament fixation anchor</strong></td>
<td>A non-absorbable, implantable device used for bonding one end or both ends of the ligament, the tendon or an artificial ligament to the bone(s). Usually, it is made of metal or ceramic.</td>
<td>36174003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable fixation washer</strong></td>
<td>A non-absorbable device intended to be used with bone fixation devices such as bone screws and bolts to enhance fixation or prevent soft tissue damages. The device is usually made of metals, polymer or reinforced polymer.</td>
<td>36198003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Spinal internal fixation system</strong></td>
<td>A device consisting of rods, plates, hooks, screws (including pedicle screw), connectors, wire, cables, and the other components. The device is used for spinal fixation, support, or alignment correction. The device is usually made of metals, polymer and the other materials. The device may be used for fixation of bone fractures, degenerative disease, or congenital anomalies.</td>
<td>37272003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable tibia intramedullary fixation nail</strong></td>
<td>A rod made of metal or other material. The device is intended to be inserted into the tibial medullary cavity, serving as a fixation device to keep both ends of the fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. The device is equipped with many components: and some devices are of the locking-type which improves fixation of bone fragments both proximally and distally: some are of the non-locking-type.</td>
<td>38152000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable humerus intramedullary fixation nail</strong></td>
<td>A rod made of metal or other material. The device is intended to be inserted into the medullary cavity of the humerus, forearm bones, clavicle, etc., serving as a fixation device to keep the both ends of the fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. In addition, some types are locking devices with many components that support fixation of proximal and distal fractured bone, while others are non-locking devices.</td>
<td>38153000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Intracorporeal fixation device set</strong></td>
<td>A device dedicatedly manufactured for specific patients. The sizes, designs or materials are different from those of an ordinary device. Typical examples include a dedicated-order device of which only one is produced, such as an intramedullary rod to reinforce the knee joint long enough to reach from the femur (proximal end) to the tibia (distal end). It is manufactured in compliance with the present regulations. This is not included in the category of custom-made, artificial joint sets.</td>
<td>38159000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Medical Device Type</td>
<td>Description</td>
<td>U.S. Code</td>
<td>FDA Classification</td>
<td>Applicable</td>
<td>Remarks</td>
</tr>
<tr>
<td>----------------------------------------------</td>
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<tr>
<td><strong>Spinal cage</strong></td>
<td>A device used to replace, correct or repair the height of the spinal column instead of an intervertebral disc or a portion of the intervertebral body. Usually, it is made of metal, polymer, absorbable materials, other artificial materials, biological materials, or a combination of these materials.</td>
<td>38161003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bone fixation band</strong></td>
<td>A wire, cable or band, etc. used to bind and suture the bone and the soft tissue, to fix the bone and an implant(s), and to fix bone to bone. It is made of metal or polymer.</td>
<td>70501000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Head prosthesis fixation material</strong></td>
<td>Materials used to fix head prostheses (a facial prosthesis) to the face, including an eye prosthesis, nasal prosthesis, and ear prosthesis. They are composed of plates to be fixed to the cranial, screws, a support (an anchor) for fixation, etc.</td>
<td>70503000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Implantable fixation cable</strong></td>
<td>A non-absorbable cable used for bone fixation (twisted or braided). The cable is used as an internal fixation device. In principle, fastening is performed using clamps in order to recombine fractures or osteotomies such as olecranon, patella, medial malleolus and greater trochanter, or to fix the spine. The device also includes components such as implants used in combination with cables. The device is usually made of a metal or polymer.</td>
<td>70504000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Sacral hemostasis pin</strong></td>
<td>An implantable device used to control excessive hemorrhage from the presacral blood vessels. This device has a thumbtack-like shape and made of metal (mainly titanium).</td>
<td>70506000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cranial resinous compound</strong></td>
<td>A resin-like substance used to reconstruct the cranial after a neurosurgical procedure.</td>
<td>16131000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Orthopaedic bone cement</strong></td>
<td>A substance usually made of methyl methacrylate, polymethyl methacrylate (PMMA), methacrylic acid ester, or copolymers containing PMMA and polystyrene. It is used in arthroplasty to fix artificial joints made of polymer, metal or ceramic to the in vivo bone. It may be used as a filling material in the damaged site of bone lesions. It may contain an antibiotic.</td>
<td>35217000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Total joint arthroplasty cement spacer</strong></td>
<td>A device made of cement usually placed in the articular cavity temporarily to prevent bone-to-bone contact and contraction of the soft tissues after surgical repair of all joints.</td>
<td>44267000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Artificial bone cap</strong></td>
<td>An implantable device used to cover the amputation stump of the bone such as the humerus or the tibia to suppress bony overgrowth after amputation in young patients.</td>
<td>16082000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Total ankle prostheses</strong></td>
<td>An artificial joint used to replace the major articular surface of the foot joint. Usually, it is made of metal, ceramic, carbon, polymer or of a combination of these materials. A constrained, semi-constrained, or non-constrained type is available. A cement or cementless fixation type is available.</td>
<td>32837000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-absorbable tendon prosthesis</strong></td>
<td>An implantable device to replace or repair loss or damage of the tendon to restore its function. This is made of non-absorbable materials.</td>
<td>32869003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Maxillofacial prosthesis</strong></td>
<td>A device used to repair or replace the maxilla. It is usually made of metal, but it may also be made of polymer.</td>
<td>33168000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hip prosthesis acetabular support component</strong></td>
<td>A device that may be in the form of an acetabular support ring, sheet or mesh. The device is used to support the prosthetic acetabular component where there has been an acetabular damage. The device is usually made of metal or polymer.</td>
<td>33179000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hip prosthesis bone cement restrictor</strong></td>
<td>A device used in the distal femoral cavity, or with an acetabular component, in order to limit leakage of bone cement. The device is usually made of polymer containing polymethyl methacrylate (PMMA).</td>
<td>33180000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Reference Number</td>
<td>Classification</td>
<td>Vonal Code</td>
<td>Applicability</td>
</tr>
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</tr>
<tr>
<td>Total wrist prosthesis</td>
<td>An artificial joint to replace or substitute for the surface of the finger joint. A constrained, semi-constrained, or non-constrained type is available. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.</td>
<td>33705000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Cement spacer</td>
<td>A non-absorbable device used to maintain the thickness of bone cement (e.g., polymethyl methacrylate [PMMA]) between the implanted artificial joint, etc. and the bone. Usually, it is molded with polymer or bone cement materials (PMMA).</td>
<td>33982003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Cement bone plug</td>
<td>A non-absorbable device used as the blocker (used as a cement restrictor) to seal the medullary cavity in order to limit the pathway of bone cement. It is made of polymethyl methacrylate (PMMA), polyethylene (UHMWPE), etc. A metal marker may be incorporated into it.</td>
<td>34031003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ankle prostheses talar component</td>
<td>An artificial foot joint component attached to the talus in order to replace or repair the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.</td>
<td>34108000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Chin prosthesis</td>
<td>A device implanted in the soft tissue of the lower jaw bone to correct deformation of the lower jaw or improve appearance. Usually, it is made of polymer.</td>
<td>35261000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ankle prostheses tibial component</td>
<td>An artificial foot joint component attached to the distal tibia in order to replace or repair the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.</td>
<td>35662000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Wrist prosthesis carpal component</td>
<td>An artificial joint component that replaces the support surface of the carpal bone and forms an artificial joint between an artificial radius and ulna. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.</td>
<td>35663000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tendon spacer</td>
<td>A non-absorbable device used to separate tissues and prevent physical contact. This prevents the tendon from adhering to adjoining tissues, and allows it to move freely.</td>
<td>35671003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Total ossicular prosthesis</td>
<td>A device or system consisting of multiple devices that are intended to replace the ear ossicle for correction or restoration of hearing. Usually, it is made of biological or synthetic materials.</td>
<td>35674000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Orbital rim prosthesis</td>
<td>A device used to reconstruct the orbital floor or the orbital margin. Usually, it is made of stainless steel, titanium or titanium alloy. It may be made of other materials.</td>
<td>35677000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Zygomatic prosthesis</td>
<td>A device used to replace or repair the cheekbone. Usually, it is made of metal. It may also be made of polymer.</td>
<td>35678000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Local ossicular prosthesis</td>
<td>A biological or synthetic device used for replacement of the ossicle in the middle ear, etc.</td>
<td>35690000</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Wrist prosthesis radial/ulnar component</td>
<td>An artificial joint component to replace the support surface of the carpal bone and the articular support surface between the distal radius and ulna and the carpal bones. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.</td>
<td>35727000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Radial head prosthesis</td>
<td>A device used to replace the entire or a portion of the proximal radius (radial head). A cement or cementless fixation type is available. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials.</td>
<td>35966003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Stage</td>
<td>Applicable</td>
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<tr>
<td>Total temporomandibular joint prosthesis</td>
<td>An implantable artificial joint used to reconstruct the bilateral temporomandibular joint. Usually, it is made of artificial materials including metal and polymer.</td>
<td>36042000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Temporomandibular disk prosthesis</td>
<td>An implant or articular disk inserted as an interposition material in order to form a contact between the mandibular condyle and the glenoid fossa in the temporomandibular joint. Usually, it is made of artificial materials including metal and polymer.</td>
<td>36260000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Digit prosthesis</td>
<td>An artificial joint used to replace the finger joint, thumb joint or toe joint. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A constrained, semi-constrained, or non-constrained type is available. A cement or cementless fixation type is available.</td>
<td>37845000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Joint prosthesis set</td>
<td>An artificial joint device manufactured specifically for an individual patient. The sizes, designs or materials are different from those of an ordinary device.</td>
<td>38158000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Lower limb reconstruction artificial material</td>
<td>An implant used to repair bone loss, or to reconstruct the lower extremity function in patients with extensive bone resection due to malignant tumors, etc. This includes artificial joints or the articulating parts and accessories.</td>
<td>70508000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Upper limb reconstruction artificial material</td>
<td>An implant used to repair bone loss, or to reconstruct the upper extremity function in patients with extensive bone resection due to malignant tumors, etc. This includes artificial joints or the articulating parts and accessories.</td>
<td>70509000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Anterior chamber lens</td>
<td>A device intended to be permanently implanted into the ocular cavity that is in contact with a portion of the cornea and a portion of sclera anteriorly and with a portion of the ciliary body and the iris as well as a portion of the crystalline lens from end to end of the pupil posteriorly. It is intended to replace the specified crystalline lens. Usually, it is a plastic lens and inserted into the anterior chamber of the eye after the removal of the cataractous crystalline lens.</td>
<td>35655000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Posterior chamber lens</td>
<td>A device intended to be permanently implanted into the posterior chamber of the eye to replace the specified crystalline lens and to restore vision. Usually, it is a plastic lens and which is inserted into the posterior chamber of eye after the removal of a cataractous crystalline lens.</td>
<td>35658100</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated posterior chamber lens</td>
<td>A heparin-coated device intended to be permanently implanted into the posterior chamber of the eye to replace the specified crystalline lens and to restore vision. Usually, it is a plastic lens and inserted into the posterior chamber of the eye after the removal of the cataractous crystalline lens.</td>
<td>35658200</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Multifocal posterior chamber lens</td>
<td>A device intended to be permanently implanted into the posterior chamber of the eye to replace the specified crystalline lens and to restore vision. Usually, it is a plastic lens and inserted into the posterior chamber of the eye after the removal of the cataractous crystalline lens. It has the multifocal mechanism.</td>
<td>35658300</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Posterior chamber lens with inserter</td>
<td>A posterior chamber lens or a multifocal posterior chamber lens that is pre-loaded on a single-use lens inserter.</td>
<td>35658400</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tymanostomy tube</td>
<td>A device used to replace or repair the function of the tympanic membrane.</td>
<td>33794000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tympanic membrane implant</td>
<td>A device used to replace or repair the function of the tympanic membrane of the middle ear. It may be made of synthetic materials.</td>
<td>34410000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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<tr>
<td>Auditory electrical stimulator</td>
<td>A device used to partially restore hearing in a patient with high-frequency sensorineural hearing loss or severe hearing impairment. It consists of an electrode array (inserted into the cochlea on one side), a receiver and stimulator (implanted near the ear inside the skull), a speech processor (it is attached to the outside of the body, converts sounds to electric signals and sends the signals to the receiver and stimulator.). The device equipped with the sonic stimulation function contains an acoustic unit which amplifies sounds, adjusts tone quality, and transmits the sounds to the ear mold.</td>
<td>35643000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tracheoesophageal speech valve</td>
<td>A device equipped with a companion flange inserted into the surgically formed tracheoesophageal fistula. It has a slit along the diameter on the esophagus surface of the device. It is used to utterance function rehabilitation after laryngectomy.</td>
<td>36245000</td>
<td>III</td>
<td>5-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Liquid tissue reconstructive material</td>
<td>A synthetic liquid substance to be injected or infused to fill a space for cosmetic or reconstruction purposes.</td>
<td>17876000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tympanostomy semi-permeable membrane tube</td>
<td>A small, cylindrical, hollow device to be implanted for ventilation and drainage of the middle ear, and for to prevent the inflow of liquid into the middle ear cavity. It is inserted through the tympanic membrane to allow the free passage of air between the external ear and middle ear. The tube is made of silicone elastomer or porous polyethylene, and the membrane is made of polytetrafluoroethylene.</td>
<td>33643000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable neurological stimulator electrode/lead</td>
<td>A lead insulated with non-conductive materials except in the electrode portion, designed to be implanted into the nerve tissue. It is used to establish an electrical connection between a stimulator and the tissue.</td>
<td>44040000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable incontinence stimulator electrode/lead</td>
<td>A lead insulated with non-conductive materials, designed to be implanted into the sphincter. The electrode portion is not insulated. It is used to establish an electrical connection between a stimulator and the sphincter.</td>
<td>44045000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable eyelid weight</td>
<td>An ophthalmic device that weights the eyelid or compresses the eyelid for functional recovery of the upper eyelid. It is intended to be implanted in the upper eyelid.</td>
<td>18074000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Nose prosthesis</td>
<td>A device to be inserted into the facial tissues (nose) for cosmetic or reconstruction. Usually it is made of polymeric materials.</td>
<td>31038000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Endolymphatic vessel prosthesis</td>
<td>A device used to repair or replace a portion of the endolymphatic vessel. It may be equipped with valves that send materials to one direction.</td>
<td>31931000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable middle ear mold</td>
<td>A device that is implanted for reconstruction of the middle ear cavity in eardrum repair, and works as a mold. It keeps the middle ear cavity filled with sufficient air and promotes regeneration of the middle ear mucosa. It is made of polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene.</td>
<td>31934000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable mechanical/hydraulic incontinence device</td>
<td>An implantable device used to treat urinary incontinence by adding pressure continuously or intermittently to occlude the urethra. The completely implantable type may have a static pressure pad, or consist of a system comprising a container with radiopaque liquid implanted into the abdomen, and a manual pump and valves implanted under the skin surface and connected with a tube to the adjustable pressure pad or to the cuff surrounding the urethra. It sends the radiopaque liquid from the container as needed, and it inflates the pad or cuff to compress the urethra.</td>
<td>31994000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Vas deferens prosthesis</td>
<td>A device used to repair the site of damage or obstruction in the vas deferens that sends sperm from the epididymis to the urethra. Devices for temporary use are not included.</td>
<td>31995003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Prosthesis Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Grade</td>
<td>Applicable</td>
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<tr>
<td>Ureterovesical prosthesis</td>
<td>An internal device that is implanted into the ureteral wall. The function of the sphincter is supported by increasing the volume and tensile strength of the ureteral wall. Usually, it is made of non-absorbable polymers including silicone rubber and teflon. It is applied with a catheter.</td>
<td>31998000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ear, nose, and throat (ENT) prosthesis</td>
<td>A non-absorbable device used for soft tissue replacement or repair in the ear, nose, and throat (ENT) surgery. It is made of polymers including porous polyethylene, silicone elastomer, polyurethane, and polyamide.</td>
<td>33310103</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable synthetic/carbon fibre prosthesis</td>
<td>A material made of polytetrafluoroethylene (PTFE) reinforced with carbon fiber used to produce composite materials for non-absorbable implants. In cosmetic surgery, it is used to restore the structure of bones and tissues around the jaw, nose, and eye.</td>
<td>33473103</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Intestinal splinting prosthesis</td>
<td>A rigid or flexible device used to maintain a part of the intestinal tract in situ, or maintain the damaged site of the intestinal tract in situ and protect it.</td>
<td>33806000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ocular sclera prosthesis</td>
<td>A device used to reinforce or repair a scleral defect.</td>
<td>34000000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Anal sphincter prosthesis</td>
<td>A device used to restore the function of defecation by re-controlling fecal incontinence.</td>
<td>34092000</td>
<td>III</td>
<td>5&lt;sup&gt;④&lt;/sup&gt;</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable incontinence prosthesis</td>
<td>An implantable device used to correct or control the excretory function including defecation and urination in a patient who has lost control of the excretory function.</td>
<td>34214100</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Collagen-containing implantable incontinence prosthesis</td>
<td>An implantable collagen-containing device used to correct or control the excretory function including defecation and urination in a patient who has lost control of the excretory function. It may be used for treatment of vesicoureteral reflux or a skin test.</td>
<td>34214200</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Bile duct prosthesis</td>
<td>A device used to replace or repair the duct that carries bile from the gallbladder to restore function.</td>
<td>335258000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Bladder mesh prosthesis</td>
<td>A device used to support the walls of the bladder or other replaced tissues. It is made of polymeric materials, and may have a butterfly-like shape or be V-shaped so that it fits the anatomical structure(s).</td>
<td>335259000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Cervical cerclage prosthesis</td>
<td>A device used for the support or functional recovery of the uterine cervix.</td>
<td>335260000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Ear prosthesis</td>
<td>A device intended to implant into the tissues for external ear reconstruction usually for cosmetic reasons. It may also be used to reinforce the hearing mechanism. The external component is usually made of polymeric materials. The internal component may be fixed with screws.</td>
<td>335262000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Esophageal prosthesis</td>
<td>A tubular device to be inserted into the esophagus for replacement or repair to restore function.</td>
<td>335263000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Fallopian tube prosthesis</td>
<td>A device that replaces or restores the function of the fallopian tube.</td>
<td>335264000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Larynx prosthesis</td>
<td>A device used for replacement and restoration of the laryngeal function, or for maintenance of patency of the larynx. It is made of stainless steel, polymer, etc.</td>
<td>335268000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Muscle prosthesis</td>
<td>A device a part or the whole of which is inserted into the body to replace muscle tissue for prosthetic, therapeutic or experimental purposes.</td>
<td>335272000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Approval</td>
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</tr>
<tr>
<td>Testicular prosthesis</td>
<td>A device in the shape of a testicle. It is implanted into the scrotum to restore cosmetic appearance of the testicle. It works aesthetically and prevents psychogenic sequelae. It may be entirely made of polymer including silicone rubber, or it may be in the form of a silicone membrane sac filled with silicone oil. It may be made of metal.</td>
<td>35277000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tracheobronchial prosthesis</td>
<td>A device used to replace the whole or a part of the trachea and bronchus for functional recovery.</td>
<td>35278000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Urethral prosthesis</td>
<td>A device used to replace or repair the urethra.</td>
<td>35279000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Urethral sphincter prosthesis</td>
<td>An internal device that is indicated for incontinence. It is intended to support or replace the natural urethral sphincter. Usually, it consists of a single cuff or double cuff surrounding the urethra, a reservoir containing a hydraulic liquid including saline solution (or the reservoir may contain a radiopaque agent), and a manual pump. It is mainly made of non-absorbable polymer materials.</td>
<td>35280000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Tracheal prosthesis</td>
<td>A tubular device used to replace the natural trachea in airway reconstruction.</td>
<td>35458000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Eustachian tube prosthesis</td>
<td>A device used to replace or repair the eustachian tube from the middle ear to the pharynx.</td>
<td>35512000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Urethral antireflux prosthesis</td>
<td>A device used to treat severe gastroesophageal reflux disease.</td>
<td>35695000</td>
<td>III</td>
<td>5-4</td>
<td>applicable</td>
</tr>
<tr>
<td>Intraocular drain</td>
<td>An artificial drain to be implanted into the eye to lower elevated intraocular pressure.</td>
<td>36099000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Penile prosthesis</td>
<td>An internal device that is indicated for erectile dysfunction. It is used to obtain expansion and stiffness of the penis. This is a hydraulic device, and made of silicone rubber or other polymers. It is implanted in the penis. It consists of a reservoir containing liquids including saline solution (a radiopaque agent may be added) to be implanted in the abdomen and one or multiple inflatable cylinders connected to a manual pump to be implanted beneath the scrotal skin.</td>
<td>36250000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Rod penile prosthesis</td>
<td>An internal device that is indicated for erectile dysfunction. It is used to obtain permanent expansion and stiffness of the penis. It is made of silicone rubber or other polymers, and has one or multiple rod-shaped bodies. It may be rigid or semi-rigid and reinforced with metal.</td>
<td>36251000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracorneal ring</td>
<td>A ring-shaped device that is inserted into the cornea to correct refractive error including myopia by flattening the corneal curvature.</td>
<td>36291000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Corneal prosthesis</td>
<td>A device used to replace the cornea and to restore vision.</td>
<td>42525000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Eye valve prosthesis</td>
<td>An artificial, membrane-like device used to replace the valves in the human eye.</td>
<td>42526000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Implantable lesion identification marker</td>
<td>A device in the form of a wire, needle, clip or bead intended to be implanted in the body temporarily or permanently in order to make an identification mark that can be confirmed on a film or digital image. It is used for position determination and visualization of sites of interest such as tumors or lesions. It is made of materials compatible with those used with the imaging system including a magnetic resonance imaging (MRI) system, X-ray system and nuclear medicine system.</td>
<td>40808000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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</tr>
<tr>
<td>Non-central circulatory embolization implant kit</td>
<td>A device or a collection of devices used in combination to implant an embolization implant that forms a permanent or temporary embolus (to stop blood flow) in the artery or the vein in the non-central circulatory system. Usually, it consists of an embolization implant, an inserter, and a dedicated syringe(s). It may contain other devices necessary for the surgery. This device is for single-use.</td>
<td>70512000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Retinopexy prosthesis</td>
<td>A sterile ophthalmic implant device used to locally reshape and fix the eyeball in order to reattach a detached retina onto the choroid.</td>
<td>70513000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Hemodialysis system</td>
<td>A system used to perform hemodialysis with a dialyzer.</td>
<td>34995000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Control/monitor for dialysis system</td>
<td>A device for monitoring parameters including dialysis fluid flow rate, temperature, and venous pressure during hemodialysis by artificial kidney.</td>
<td>36424000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Multi-patient dialysis fluid delivery system</td>
<td>A device that prepares dialysis fluid for hemodialysis using an artificial kidney, capable of supplying dialysis fluid for two or more patients.</td>
<td>34993000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Individual dialysis console</td>
<td>A device with functions necessary to perform hemodialysis on one patient. Adsorbent-based devices that recirculate dialysis fluid are also included.</td>
<td>34994010</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Multipurpose dialysis system</td>
<td>A device for blood dialysis monitoring or a single-patient blood dialysis filter system that may be capable of performing hemodialysis, hemofiltration, hemofiltration, or slow continuous hemofiltration.</td>
<td>34994020</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dialysate fluid flowmeter for dialysis system</td>
<td>An essential component of a dialyzer. It measures the flow rate of dialysate fluid in the dialyzer to confirm that the flow rate is appropriate.</td>
<td>32123000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dialysate fluid level detector for dialysis system</td>
<td>An essential unit of a dialyzer. It detects the volume of dialysate fluid in the dialyzer and gives a warning sound when the volume is inappropriate.</td>
<td>32126000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood level detector for dialysis system</td>
<td>An essential unit of a dialyzer. It detects the blood volume in arterial and venous chambers in the extracorporeal circulation circuit during dialysis and gives a warning sound when the volume is inappropriate.</td>
<td>32127000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood leak detector for dialysis system</td>
<td>An essential unit of a dialyzer. It detects a blood leak into the dialysate fluid discharging line in the dialyzer and gives a warning sound when blood is detected in the discharging line.</td>
<td>32128000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dialysate fluid temperature monitor for dialysis system</td>
<td>An essential unit of a dialyzer. It monitors the temperature of the dialysate fluid in the extracorporeal circulation circuit and gives a warning sound when an abnormal temperature is detected.</td>
<td>32156000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Pillow pressure alarm for hemodialysis system</td>
<td>A device that gives a warning sound or a visual signal when a decrease in the arterial blood volume is detected in the arterial blood tube set connected to a hemodialysis system based on a decrease in the blood flow rate. It consists of a small-sized pillow that detects a decrease in blood pressure caused by a decrease in the blood flow rate. These devices can employ existing techniques.</td>
<td>32124000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrical conductivity measuring instrument for dialysate fluid</td>
<td>A device used to determine the concentration of dialysate fluid supplied to a dialyzer based on the measurement of electrical conductivity of dialysate fluid (usually, it is electrically measured). It may be a component of a dialyzer or an independent device.</td>
<td>34998000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood line clamp for dialysis system</td>
<td>A unit used to handle the blood line clamp during dialysis. Usually, this unit is installed in a complete dialysis system.</td>
<td>35684000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>11 Code</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Blood circulation unit for dialysis system</td>
<td>A unit used to handle the blood circulation during dialysis. Usually, this unit is installed in a complete dialysis system.</td>
<td>36428000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Air bubble/foam guard for dialysis system</td>
<td>A dedicated device that works with a dialyzer. It is intended to give a warning to stop the connected pump mechanism when a bubble is detected in the blood before the blood is returned to the patient.</td>
<td>36437000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Replenisher pump</td>
<td>A device that injects replenishing fluid in hemodiafiltration, hemofiltration, or slow continuous hemofiltration.</td>
<td>70517000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Extracorporeal circulation hematocrit monitor</td>
<td>A device that measures the hematocrit level in the blood (the percentage of erythrocytes) invasively during extracorporeal circulation during dialysis or open heart surgery.</td>
<td>70518000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Hemodiafiltration system</td>
<td>A device used for blood purification with a hemiafilter. Functionality for controlling ultrafiltration volume and infusion volume is incorporated into a regular hemodialysis system.</td>
<td>70520000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Hollow fiber dialyser</td>
<td>A device used for removing wastes that have accumulated in blood due to abnormal renal function or renal failure. Removal of wastes works by moving wastes from blood into the dialysis fluid across a semi-permeable membrane capable of allowing blood and dialysis fluid to circulate in separate compartments. The membrane consists of hollow fibers. The blood passes through the lumen of hollow fibers, while the dialysis fluid passes outside the hollow fibers, removing impurities.</td>
<td>35004000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Parallel-plate dialyser</td>
<td>A medical device used for removing wastes that have accumulated in blood due to abnormal renal function or renal failure. Removal of wastes works by moving wastes from blood into the dialysis fluid across a semi-permeable membrane capable of allowing blood and dialysis fluid to circulate in separate compartments. The membrane consists of flat-sheet membranes. With the blood and dialysis fluid flowing separately in a space between the flat-sheet membranes, waste products are removed from the blood.</td>
<td>35005000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart-lung bypass system</td>
<td>A set of devices that perform mechanical circulatory assist and make cardiac surgery easier by by-passing the heart during open heart surgery. Its fundamental function is to add oxygen to the venous blood and return the oxygenated blood to the arterial circuit with a pump. Usually, it has a few functions including intracardiac aspiration, filtration, and temperature management. The important modules and components of this set include a pump, a temperature regulator, various types of monitors. This is manufactured as a single unit or a device consisting of modules is also available.</td>
<td>35099000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Roller pump for heart-lung bypass</td>
<td>A unit of components of a heart-lung bypass system. It injects (circulates) the extracorporeal blood flow through a roller-like mechanism that injects blood into an extracorporeal tube set connected to the other parts of the oxygenator or the artificial heart-lung system for the purpose of gas exchange and reinjection.</td>
<td>36347000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Console for heart-lung bypass</td>
<td>One of the modules of a heart-lung bypass system, or a primary mounting unit. With other units being installed in this unit, a complete system is formed. This will work as the basic workstation that can control and monitor all functions.</td>
<td>36373000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Mark</td>
<td>Applicability</td>
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<tr>
<td><strong>Driving unit for extracorporeal circulation assist centrifugal pump</strong></td>
<td>A specifically manufactured centrifugal pump that is used to maintain blood circulation in a patient with heart failure. It supports circulation (blood circulation support during heart failure) in a patient who is dependent on artificial support in order to maintain cardiac function. The dependence on artificial support is due to impaired cardiac function. This device is used to temporarily support recovery of cardiac function during or after open heart surgery. There is a type that has various monitoring functions.</td>
<td>70523000</td>
<td>III</td>
<td>3-2</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated heart-lung bypass heat exchange</strong></td>
<td>A heparin-coated device that consists of a heat exchange system used during extracorporeal circulation. This device is intended to heat or cool the blood or perfusate in cardiopulmonary bypass surgery or for treatment.</td>
<td>11973213</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated heart-lung bypass blood reservoir</strong></td>
<td>A heparin-coated device used as a part of a heart-lung bypass unit or in conjunction with other devices during temporary extracorporeal circulation. It maintains a blood reserved for extracorporeal circulation. It may have a filtering function. This device is for single-use.</td>
<td>31710923</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated heart-lung bypass defoamer</strong></td>
<td>A heparin-coated device used to remove bubbles from the blood during cardiopulmonary bypass surgery. It is used with an oxygenator that adds the required amount of oxygen to the blood before it is returned to the patient.</td>
<td>31711213</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heart-lung bypass gas control unit</strong></td>
<td>One of the modules of a heart-lung bypass system. It controls and measures the rate of gas flow that is supplied to an oxygenator. It is calibrated for a specific gas, and has high precision at a low flow rate. It may work as a flowmeter.</td>
<td>31714000</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated heart-lung bypass circuit filter</strong></td>
<td>A heparin-coated filter to prevent particles and blood clots from entering the circulation, which may block extracorporeal circulation. This filter may be used for trapping air bubbles.</td>
<td>33309203</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Filter for heart-lung bypass hemoconcentration</strong></td>
<td>A filter used to remove crystalline particles from a priming solution and to concentrate the patient’s blood before the cardiopulmonary bypass device is removed from the patient in a heart-lung bypass system.</td>
<td>36089000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heart-lung bypass pressure gauge</strong></td>
<td>One of the modules of a heart-lung bypass system. It electrically or mechanically measures the blood pressure in the tube circuit.</td>
<td>36356000</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heart-lung bypass temperature control unit</strong></td>
<td>One of the modules of a cardiopulmonary bypass device. It measures and displays the temperature of the fluid and the blood with various temperature probes connected to the device in order to monitor the temperature of the fluid and the blood at various points. It may control the temperature (e.g., the temperature of the fluid that flows in and out from the heat exchanger).</td>
<td>36374000</td>
<td>III</td>
<td>3&lt;1,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heart-lung bypass circuit system</strong></td>
<td>A packed, sterile set of a heart-lung bypass circuit system used in cardiopulmonary bypass surgery and for assisting circulation. Usually, it consists of a tube, a bubble-removing device, a venous and intracardiac blood reservoir, an oxygenator, a blood filter, a priming solution filter, an in-line blood gas sensor, a heat exchanger, safety valves, a centrifugal pump, and catheters, etc.</td>
<td>70524100</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated heart-lung bypass circuit system</strong></td>
<td>A packed, sterile, heparin-coated set of a heart-lung bypass circuit system used in cardiopulmonary bypass surgery and for assisting circulation. Usually, it consists of a tube, a bubble-removing device, a venous and intracardiac blood reservoir, an oxygenator, a blood filter, a priming solution filter, an in-line blood gas sensor, a heat exchanger, safety valves, a centrifugal pump, and catheters, etc.</td>
<td>70524200</td>
<td>III</td>
<td>3&lt;14</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Heparin-coated single-use heart-lung bypass defoamer</td>
<td>A heparin-coated system used to remove air bubbles from blood during cardiopulmonary bypass procedures. The device is used with an oxygenator, which adds necessary oxygen to blood before returning blood to the patient. The device is intended for single-use.</td>
<td>31711223</td>
<td>III</td>
<td>3-①,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated single-use heart-lung bypass heat exchange</td>
<td>A heparin-coated device consisting of a heat exchange system used during extracorporeal circulation. It heats or cools the blood or perfusate during cardiopulmonary bypass surgery or for treatment. This device is for single-use.</td>
<td>11973223</td>
<td>III</td>
<td>3-①,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart-lung bypass in-line gas monitor</td>
<td>One of the modules of a heart-lung bypass system. It is used to measure and monitor the gas concentration(s) in the circulating blood. It is used with an appropriate sensor.</td>
<td>31685000</td>
<td>III</td>
<td>10-④,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated heart-lung bypass in-line gas monitor</td>
<td>One of the heparin-coated modules of a heart-lung bypass system. It is used to measure and monitor the gas concentration(s) in the circulating blood. It is used with an appropriate sensor.</td>
<td>31685009</td>
<td>III</td>
<td>10-④,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart-lung bypass in-line blood gas sensor</td>
<td>A device used concurrently with a heart-lung bypass system for detection and transmission of certain measurable signals. The signals are displayed on the base unit, which shows the amount of gas in the blood.</td>
<td>31715100</td>
<td>III</td>
<td>10-④,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated heart-lung bypass in-line blood gas sensor</td>
<td>A heparin-coated device used concurrently with a heart-lung bypass system for detection and transmission of certain measurable signals. The signals are displayed on the base unit, which shows the amount of gas in the blood.</td>
<td>31715200</td>
<td>III</td>
<td>10-④,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart-lung bypass pulsatile pressure generator</td>
<td>One of the components of a heart-lung bypass system. It is an electronic device that provides electricity to the roller pump of the system and controls the pump. The roller pump functions in a pulsatile manner. Therefore, it imitates the natural movement of the heart.</td>
<td>35101000</td>
<td>III</td>
<td>9-②,④</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart-lung bypass air/fluid level detector</td>
<td>A device that gives a warning or stops the roller pump connected to the device when air (e.g., bubbles) is detected in the perfusion line or when the fluid level in the reservoir of a heart-lung bypass system is too low.</td>
<td>35440000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Extracorporeal circulation blood parameter monitor</td>
<td>A device that measures substances in the blood or the temperature of the blood during extracorporeal circulation in open heart surgery.</td>
<td>70526000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Extracorporeal circulation blood parameter monitor measuring cell</td>
<td>A cell that measures substances in the blood or the temperature of the blood during extracorporeal circulation in dialysis and open heart surgery. Usually, it is installed in the extracorporeal circulation circuit before use. It is used in combination with the hematological parameter monitor for extracorporeal circulation.</td>
<td>70527000</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated extracorporeal circulation blood parameter monitor measuring cell</td>
<td>A heparin-containing cell that measures substances in the blood or the temperature of the blood during extracorporeal circulation in dialysis and open heart surgery. Usually, it is installed in the extracorporeal circulation circuit before use. It is used in combination with the hematological parameter monitor for extracorporeal circulation.</td>
<td>70528000</td>
<td>III</td>
<td>10-④,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Extracorporeal bubble oxygenator</td>
<td>A device used for gas exchange between the blood and gas environment in order to meet the gas exchange requirements in the patient. Usually, it is used in open heart surgery.</td>
<td>35100000</td>
<td>III</td>
<td>3,④</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Extracorporeal membrane oxygenator</strong></td>
<td>A device used during open heart surgery, in the treatment of respiratory failure or cardiorespiratory failure (in adults), or for the care of high risk newborns in whom conventional respiratory/medical management procedures are not effective. Extracorporeal oxygenation of blood is performed using a special membrane oxygenator, and the procedure requires a catheter to be placed into a peripheral vessel.</td>
<td>17643100</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated extracorporeal membrane oxygenator</strong></td>
<td>A heparin-coated device used in open heart surgery, to treat a patient (adults) with respiratory failure or cardiopulmonary failure, or in a high-risk neonate for whom conventional pulmonary and medical management is ineffective. Addition of oxygen to the blood outside the body is performed with a special membrane oxygenator. A catheter needs to be inserted into a peripheral vessel.</td>
<td>17643200</td>
<td>III</td>
<td>3,14</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hemofilter</strong></td>
<td>A device to remove excess metabolic products or water from blood, without using dialysis fluid, based primarily on the principle of ultrafiltration using a semi-permeable membrane. The device is intended for single-use.</td>
<td>70529000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Adsorption hemoperfusion column</strong></td>
<td>A device used with a dedicated device that removes toxins, etc. from the blood of a patient. This is a column, and usually used exclusively for removal of a specific toxin or a series of toxins. It is made of absorbable or adsorptive materials. This device is for single-use.</td>
<td>34422000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Membrane plasma separator</strong></td>
<td>A device that separates the plasma from the whole blood using a membrane. It does not allow blood cells to pass. This device is for single-use.</td>
<td>70530000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Membrane plasma component separator</strong></td>
<td>A device that separates the components in the plasma using a membrane. This device is for single-use.</td>
<td>70531000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Adsorption plasma perfusion column</strong></td>
<td>A device that removes pathogenic substances, etc. using adsorbents from the plasma previously separated. This device is for single-use.</td>
<td>70532000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Haemoconcentrator</strong></td>
<td>A device for concentrating blood components usually through the removal of water and electrolytes, used in the treatment of fluid overload or during heart surgery that utilizes extracorporeal circulation.</td>
<td>44020000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Blood cell washer bag</strong></td>
<td>A bag used for blood washing or separation of a cell component from a mixture of blood cells. This device is for single-use. It is installed in an appropriate base unit before use.</td>
<td>16752000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Autotransfusion blood cell wash set</strong></td>
<td>A disposable set used to process the autologous blood with an autologous blood recovery system before reinjection of the blood. This device is for single-use.</td>
<td>17605000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Apheresis filter</strong></td>
<td>A filter used to separate and trap blood components. This device is for single-use.</td>
<td>36194000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Selective plasma component adsorber</strong></td>
<td>A device that selectively absorbs and removes pathogenic substances from the plasma previously separated in a patient. Usually it is used with a membrane plasma separator during extracorporeal circulation. After the pathogenic substances are adsorbed and removed, the remaining plasma is returned to the patient. This device is for single-use.</td>
<td>70533000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Slow continuous hemofilter</strong></td>
<td>A device that performs slow continuous hemofiltration, hemodialysis, or hemodiafiltration over a longer period of time than normal hemodialysis treatment. This device is intended for single-use.</td>
<td>70534000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Code Numbers 11-13</td>
<td>Regulation</td>
<td>Applicable</td>
<td>Notes</td>
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<td></td>
</tr>
<tr>
<td>Endotoxin removal adsorption hemoperfusion column</td>
<td>70535000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A device that selectively adsorbs and removes blood endotoxins from the blood. This device is for single-use.</td>
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<tr>
<td>Hemodiafilter</td>
<td>70536000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A device to remove body fluids and wastes from blood using a semi-permeable membrane, based on the principles of ultrafiltration and diffusion using a perfusate. The amount of water lost by ultrafiltration is compensated by fluid replacement. The device is intended for single-use.</td>
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<tr>
<td>Cytapheresis column</td>
<td>70537000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A device that removes blood cells from patient's blood. This device is for single-use.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Hemofiltration system</td>
<td>35453000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used to perform blood purification using hemofilter.</td>
<td></td>
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</tr>
<tr>
<td>Blood purifier for adsorption hemoperfusion</td>
<td>35104010</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used to remove toxins from the blood by passing the blood through materials (adsorption hemoperfusion column) that absorb (or adsorb) a specific toxin or a series of toxins.</td>
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</tr>
<tr>
<td>Unit for endotoxin removal adsorption hemoperfusion</td>
<td>35104020</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used for blood purification with an adsorption type blood purification device for endotoxin removal.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Plasma separation unit</td>
<td>36426000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used for blood purification with a membrane plasma separator, a membrane plasma fractionator, or a selective plasma component adsorber.</td>
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</tr>
<tr>
<td>Albumin apheresis unit</td>
<td>16405000</td>
<td>III</td>
<td>11-①,14</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used to separate the blood collected from a donor or a patient into its various components. It mixes the collected blood with anticoagulants and performs processing including separation of plasma, platelets, erythrocytes, and leukocytes. Usually, this processing is performed while the device is connected to the donor or patient, and the unprocessed components are returned to the patient.</td>
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</tr>
<tr>
<td>Centrifugal apheresis unit</td>
<td>70538000</td>
<td>III</td>
<td>11-①,14</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device that collects the whole blood in a person, centrifugally separates specific blood components, and returns the remaining blood to the person. It performs collection, separation and return of blood.</td>
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</tr>
<tr>
<td>Centrifugal hemoperfusion unit</td>
<td>70539000</td>
<td>III</td>
<td>11-①,14</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A centrifugal-type blood purifier that performs processing such as washing and concentration of blood components, etc.</td>
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</tr>
<tr>
<td>Centrifugal blood component sampling unit</td>
<td>70540000</td>
<td>III</td>
<td>11-①,14</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device that centrifugally separates specific blood components from human whole blood collected. In this process, the unprocessed components are usually disposed of and not returned to the person.</td>
<td></td>
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<tr>
<td>Slow continuous hemofiltration system</td>
<td>70541000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used for blood purification with extracorporeal circulation using slow continuous hemofilter.</td>
<td></td>
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</tr>
<tr>
<td>Blood cell removal unit</td>
<td>70542000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used to remove blood cells using a cytapheresis column.</td>
<td></td>
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</tr>
<tr>
<td>Ascites filtration and reinfusion system</td>
<td>70543000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device that withdraws ascitic fluid or pleural effusion from a patient in advance, filtrates and concentrates it with an ascites filter or an ascites concentration device, circulates the body fluid extracorporeally, and returns it to the blood.</td>
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</tr>
<tr>
<td>Multipurpose blood treatment unit</td>
<td>70544000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>A device used for multi-purpose processing of the blood or body fluid including blood purification or blood cell removal using a membrane plasma separator, a slow continuous hemofilter, cytapheresis column or ascites filter, etc.</td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Date of Application</td>
<td>Applicability</td>
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<tr>
<td>Heparin-coated hemodialysis blood tubing</td>
<td>A single-use sterilized set using heparin intended for hemodialysis. Usually, it consists of a tube assembly (connectors, clamps, etc.) necessary for introducing the blood or other solutions through a vascular access device into an appropriate dialyzer/dialysis system and for circulating.</td>
<td>34999203</td>
<td>III</td>
<td>2-①,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Heparin-coated tube connector</td>
<td>A device used to mutually couple and connect 2 tubes. It is a heparin-coated connector.</td>
<td>70545203</td>
<td>III</td>
<td>2-②,14</td>
<td>applicable</td>
</tr>
<tr>
<td>Pump driving unit for circulatory assist balloon</td>
<td>A dedicated pumping device that controls an inflatable balloon that is inserted into the descending aorta. Precisely synchronized with the cardiac rhythm, this device supports cardiac function by mitigating the so-called “cardiac afterload” that occurs subsequent to the increase of coronary blood flow. It supports the circulation (supporting the blood circulation in cardiac insufficiency) in a patient who is dependent on artificial support for maintenance of cardiac function. Artificial support is required because of a deteriorating cardiac function (usually, after open heart surgery).</td>
<td>36340000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dialysis apheresis unit</td>
<td>A device that is connected with a dialyzer during dialysis. It filtrates the blood and separates the plasma, and extracts specific substances in the plasma (e.g., LDL-cholesterol). Then, the plasma is passed through the filtration column in the device and the specific substances that are combined with various substrates are extracted.</td>
<td>36344000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Gas-powered pulmonary resuscitator</td>
<td>A portable device used for ventilation or assisted ventilation in a patient with apnea or respiratory failure. Usually, it is used in an ambulance or an emergency department. It is connected to a compressed oxygen supplier. It is equipped with a compressed gas tube, a breathing circuit and a mask, or a connector for endotracheal tube attachment. The gas model may have a manual or automatic pressure cycling function.</td>
<td>13366000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ventilator for general-purpose</td>
<td>A device equipped with an automatic circulatory function that supports and manages alveolar ventilation by supplying an appropriate amount of gas to the respiratory airway. The respiratory gas is supplied to the airway of a patient via a mouthpiece, a mask, and an endotracheal tube. It can provide respiratory support in multiple and various situations (e.g., anesthesia, intensive care, neonate care, transportation, high frequency ventilation, special purposes related to specific disease). It is used with a breathing circuit.</td>
<td>70561000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ventilator for high-frequency</td>
<td>An automatic circulator used to support or manage alveolar ventilation at a rate considerably higher than the physiological respiratory rate and with a tidal volume less than the anatomical dead space. Usually, it functions independently. The high frequency ventilation is superimposed on normal ventilation frequency with this device. Therefore, some types are used with an intensive care ventilator, and others are used in a patient with ventilation complications.</td>
<td>15783000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Manually-operated jet ventilator</td>
<td>A hand-held device used for ventilation in an emergency when complete or partial airway obstruction occurs, or when a rigid bronchoscope is used. The patient is ventilated with air or oxygen using jet ventilation (gas is discharged in small amounts, rapidly and continuously) via a dedicated catheter cannula. The device can be operated with compressed air.</td>
<td>17865000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Grade</td>
<td>Applicability</td>
<td>Applicability</td>
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<tr>
<td>Negative-pressure ventilator</td>
<td>An automatic circulator used to support or manage vesicular breathing. It puts a negative pressure on the exterior surface of the chest wall and expands the chest to allow air to flow into the lungs.</td>
<td>17877000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Adult ventilator</td>
<td>An automatic circulator that manages and supports alveolar breathing. It is equipped with the functions needed to perform long-term respiratory support in compliance with various breathing requirements. This is intended to be used in adult patients, but it can be used for pediatric patients as well. There is a type that can be used to support ventilation in neonates, which is an extreme case. Usually, it is equipped with pressure and volume modes of ventilation. Patients with apnea can breathe spontaneously and receive the minimum minute volume of ventilation. It has a monitor and alarm specifically designed to be used in an intensive care unit.</td>
<td>42411000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable manually-operated pulmonary resuscitator</td>
<td>A reusable manually-operated reusable device, used for ventilation or assisted-ventilation of patients who are not breathing or breathing insufficiently. The devices are usually used in an ambulance, emergency room, or the intensive care unit of a hospital. The device is equipped with an oxygen reservoir, tube, and mask, or a connector for a tracheal tube attachment.</td>
<td>17591000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Manually-operated cardiac pump resuscitator</td>
<td>A manually operated pump (operated and controlled with air pressure) used to apply a rhythmical compression to the chest (cardiac compression) in cardiopulmonary resuscitation (CPR). The same compression is gained at each compression, and the compression can be adjusted to the originally set load level in order to prevent damage to the ribs and the viscera.</td>
<td>35308000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use manually-operated pulmonary resuscitator</td>
<td>A manually-operated single-use device used for ventilation or assisted-ventilation of patients who are not breathing or breathing insufficiently. The devices are usually used in an ambulance, emergency room, or the intensive care unit of a hospital. The device is equipped with an oxygen reservoir, tube, and mask, or a connector for a tracheal tube attachment.</td>
<td>36086000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable active device-breathing circuit connector</td>
<td>A reusable device used to connect a breathing circuit with an endotracheal tube, a face mask, and other components in the breathing circuit. The device has standardized external and internal dimensions of 22 mm and 15 mm, respectively, based on the ISO standards. Therefore, there are types that come in other sizes to comply with respiratory tubes for pediatric and adults. It is made of plastic or metal. Some types are designed to allow partial rotation at the connection point. This device is connected to an active device before use. It can be reused after being subjected to an appropriate cleaning process.</td>
<td>34838003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Neonatal/pediatric ventilator</td>
<td>A dedicated automatic cycle device used to control and support alveolar ventilation that has sufficient function to provide long-term respiratory support to neonates and pediatric patients who have changeable respiratory requirements. The device is not suitable for children and adults. However, it has been designed to be particularly suitable for assisting respiration in premature babies. Usually, it has a pressure cycle mode. It enables natural respiration with a minimum minute volume when apnea occurs in a patient. This device is equipped with a monitor and an alarm designed for a high-care unit.</td>
<td>14361000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Exhaled air pulmonary resuscitator</strong></td>
<td>A device used to provide respiratory support for a patient who has a patent airway but has shallow breathing or apnea. Usually, it consists of a mouthpiece, a non-rebreathing valve or filter, and a mask. The non-rebreathing valve or one-way valve is designed to protect healthcare professionals from coming into contact with the patient's fluids, droplets and expired air.</td>
<td>17141000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ventilator for anaesthesia</strong></td>
<td>An independent-type, automatic circulator used to support and manage alveolar ventilation during general anesthesia. This device is suitable for inhalation anesthetics. It has fewer functions compared with an intensive care ventilator, and its operation is simple. However, it appropriately copes with the requirements for exchange between oxygen and carbon dioxide in order to maintain normal blood gas concentrations. This device works as a mechanical means to provide a patient with respiratory gas under control. It is equipped with an alarm that warns of the occurrences of respiratory changes or dangerous operating conditions.</td>
<td>34851000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ventilator for transportable</strong></td>
<td>A device used to support or manage alveolar ventilation. It is equipped with a self-contained gas supply mechanism designed to be operated while moving. Usually, it is portable, and it may work with a battery power source or with an air pressure source. However, it may need an external power source to use for long hours. It is mainly used for treatment in an alternate location and for emergency care during transportation or outside a hospital.</td>
<td>36289000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Continuous positive airway pressure unit</strong></td>
<td>This device is sometimes called continuous positive airway pressure (CPAP). A device that supplies a constant amount of oxygen/air at a prescribed pressure to patients, making the lungs at a state of slightly positive pressure and thereby accelerating gas exchange. The device is used, under a physician's guidance, for adult patients with sleep apnea due to airway obstruction.</td>
<td>36700000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ventilator for home use</strong></td>
<td>An automatic circulator that supports and manages alveolar ventilation. It is used by the patient at home where the patient is dependent on long-term or permanent respiratory support under the directions of a doctor. The patient or patient's family can operate. There is a gas type or an electric type.</td>
<td>36943000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bi-level positive airway pressure unit</strong></td>
<td>A device often called BIPAP (bilevel positive airway pressure) ventilator. It provides oxygen or air at a constant flow rate, and provides the maximum and minimum airway pressure during spontaneous respiration.</td>
<td>36990000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Converter for ventilator</strong></td>
<td>A device used to connect a certain type of electrically operated ventilator to a certain type of breathing circuit system, and to ensure compatibility. With this device, a ventilator and a breathing circuit manufactured by different manufacturers can be combined in an innovative way. It is useful as it allows a hospital, etc. to flexibly select a breathing circuit or breathing circuit system that makes it possible to create a new type of breathing circuit or system using the same ventilator.</td>
<td>37038000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Continuous-automatic positive airway pressure unit</strong></td>
<td>A device used to provide continuous positive airway pressure in spontaneously breathing patients, to accelerate alveolar ventilation. The device is sometimes called automatic continuous positive airway pressure (CPAP). The device is usually used for adult patients with sleep apnea due to airway obstruction, under a physician's guidance. The airway pressure is automatically controlled with a sensor at an appropriate level for CPAP.</td>
<td>37234000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>11-2</td>
<td>Applicable</td>
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<tr>
<td><strong>Anaesthesia system</strong></td>
<td>A general anesthesia supplier completely integrated for oxygen, nitrous oxide, and other medical gases. The main components include a gas supply system of high, middle, and low pressure gases, a breathing circuit (with or without a ventilator), and a gas scavenger system. It has built-in devices such as an alarm, analysis equipment, and a monitor (with an integrated circuit and display).</td>
<td>37710000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Closed-circuit anaesthesia system</strong></td>
<td>An anesthesia system specifically designed for gases that continuously come in contact with the airway in a patient. This device reuses the expired gas of a patient that has passed through carbon dioxide absorbents and returns it to the patient. To maintain equilibrium, a very small amount of fresh gas is required. This method is known as closed circulation. However, a small amount of used gas is exhausted from the closed circuit.</td>
<td>34432000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ventilator for anaesthesia system</strong></td>
<td>A type of module of an anesthesia system used to support or manage alveolar ventilation during general anesthesia. This device is suitable for inhalation anesthetics. It is able to cope well with the need to exchange oxygen with carbon dioxide in order to maintain normal blood gas concentrations while the exact amount of anesthetics is administered. This device works as the mechanical means to provide respiratory gas under control for a patient. It is equipped with an alarm that warns of the occurrence of respiratory changes or dangerous operating conditions.</td>
<td>42330000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dental anaesthesia gas delivery unit</strong></td>
<td>A unit consisting of a fresh gas supply module and a protection module for the purpose of administration of oxygen and nitrous oxide, or air in dental surgery.</td>
<td>36193000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Mixed gas anaesthesia apparatus</strong></td>
<td>A device that supplies a mixture of nitrous oxide and oxygen based on non-rebreathing anesthesia (e.g., with a demand valve mask) for painless delivery, dental surgery, postoperative pain relief, or delivery with little pain (i.e., use of pain-reducing drugs).</td>
<td>70573000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Regulator for medical gas</strong></td>
<td>A device that adjusts multiple types of medical gas to constant concentrations to deliver these gases to patients. Usually, the mixed gas is a mixture of oxygen (O2) and air or a mixture of O2 and nitrous oxide (laughing gas). In special cases, nitric oxide (NO) or nitrogen (N2) may be mixed. Adjusting to the specified concentration of one component (usually, O2), the mixed gas is precisely made, and delivered to patients through various breathing circuits/tubes.</td>
<td>36327000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vaporizer for Ethrane anaesthesia</strong></td>
<td>A device that vaporizes an anesthetic ethrane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36316000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vaporizer for Isoflurane anaesthesia</strong></td>
<td>A device that vaporizes an anesthetic isoflurane and administers the gas to a patient in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36890000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vaporizer for Ether anaesthesia</strong></td>
<td>A device that vaporizes an anesthetic ether and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36892000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vaporizer for desflurane anaesthesia</strong></td>
<td>A device that vaporizes an anesthetic desflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36979000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Vaporizer for Sevoflurane anaesthesia</strong></td>
<td>A device that vaporizes an anesthetic sevoflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36980000</td>
<td>III</td>
<td>11-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Classification</td>
<td>Applicability</td>
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<tr>
<td>Portable anaesthesia gas delivery unit</td>
<td>A portable independent unit that delivers mixed gases (oxygen, nitrous oxide, volatile inhalation anesthetics) continuously, or intermittently and monitors delivery to support the maintenance of an adequate level of anesthesia. Usually, it is used in the military or surgery under unconventional conditions.</td>
<td>44469000</td>
<td>III</td>
<td>7-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Inhalation analgesia unit</td>
<td>A device designed mainly to deliver anesthetic gas to patients or generate anesthetic vapor for inhalation. Usually, it has a built-in demand valve. It may be connected to a vaporizer calibrated for control of the volatile anesthetic concentration.</td>
<td>16953000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Stimulator for electrical anaesthesia</td>
<td>A device that introduces and maintains anesthesia in patients by applying an electric current to the nerve tissue (e.g., an electrode placed on the patient's head). It may be used in minor surgery.</td>
<td>31268000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Anaesthesia gas delivery unit</td>
<td>An independent unit that delivers mixed gases (oxygen, nitrous oxide, volatile inhalation anesthetics) continuously, or intermittently and monitors delivery to support the maintenance of an adequate level of anesthesia.</td>
<td>34846000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Hyperbaric patient chamber</td>
<td>A housing apparatus with air and gas pressures higher than standard atmospheric pressure (e.g., 2-3ATM). It is used for treatment of diseases including gas gangrene, decompression sickness and anaerobic infections, or where a condition requires a high concentration of oxygen. It may also be used to investigate the effects of compression and decompression on humans and animals.</td>
<td>12061000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Hypobaric patient chamber</td>
<td>A housing apparatus with air pressure lower than standard atmospheric pressure.</td>
<td>35115000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Oxygen therapy activator</td>
<td>A device that produces active oxygen (energy excited species of oxygen) in the form of a mixture with room air. Active water is produced as a byproduct. Inhalation of this mixed gas (together with having water as necessary) is considered useful to relieve symptoms of chronic or serious diseases (e.g., some cancers, diabetes mellitus, rheumatism, cardiovascular disease). Some physiological processes are activated.</td>
<td>37230000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Nitric oxide gas administration system</td>
<td>A dedicated system used to deliver nitric oxide to patients. It incorporates a monitor and an analyzer that can adjust the flow rate and volume of gas delivery.</td>
<td>37266000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Oxygen therapy delivery system</td>
<td>A system consisting of multiple devices that are used simultaneously to deliver oxygen based on various methods, concentrations, duration, and flow rates. It is equipped with an oxygen delivery device. It may have a flowmeter, a mask, a tube and a nasal cannula.</td>
<td>37498000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Active device oxygen condenser</td>
<td>A device that separates nitrogen from room air using an adsorption column or membrane with a large surface area. The device for a medical gas pipeline system (JIST7101) is excluded. The components of this device include a compressor, a filter and a reservoir. The oxygen concentration is adjusted according to the flow rate used. It is connected to a ventilator, etc. before it is used. Those to be simply and physically connected to a ventilator, etc. and not to control or monitor unidirectionally or mutually are excluded.</td>
<td>12873003</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary infant incubator</td>
<td>A stationary type neonatal incubator. It may have wheels but is stationed in a ward or clinical department to perform the original purpose of this device.</td>
<td>36025000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile infant heater</td>
<td>A device that has a built-in infrared heating element. It is controlled so as to emit heat uniformly to neonatal and infant patients who require the thermal environment control. It has wheels and is easily movable to various places including patient rooms, wards, clinical departments, and floors.</td>
<td>17433000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Transportable infant incubator</td>
<td>A neonatal incubator specifically designed to carry a neonate to or from a medical facility.</td>
<td>35121000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Medical Device Description</td>
<td>Definition</td>
<td>Code</td>
<td>Approval Class</td>
<td>Technical Code</td>
<td>Applicable</td>
</tr>
<tr>
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</tr>
<tr>
<td>Temporary defibrillator with pacing function</td>
<td>A device which incorporates a non-invasive, temporary pacemaker, or to which an optional pacing attachment can be connected later. It administers an electric shock and displays the electrocardiogram (ECG) to establish normal cardiac rhythm in patients with ventricular fibrillation. It has a function to administer an electrical impulse that stimulates the entire heart simultaneously for resuscitation of patients, arrhythmia treatment and temporary pacing. The ECG is displayed by the electrocardiograph monitor of the device to confirm arrhythmia and therapeutic effects.</td>
<td>17882000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Automated defibrillator</td>
<td>A device that analyzes the electrocardiogram (ECG) to determine delivery of a defibrillation shock. It is placed on a patient via adhesive defibrillation electrodes with both functions of ECG monitoring and defibrillator discharge. It provides the shock for the patient without the help of an operator.</td>
<td>35972010</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Semi-automated defibrillator</td>
<td>A device that analyzes the electrocardiogram (ECG) to determine delivery of a defibrillation shock. It is placed on a patient via adhesive defibrillation electrodes with both functions of ECG monitoring and defibrillator discharge. It informs the operator of the timing for providing the shock.</td>
<td>37805000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Manual defibrillator</td>
<td>A medical, electrical device designed to defibrillate the heart by delivering an electric pulse shock via internal or external electrodes. Usually, it has an ECG monitor, or may have a synchronizing function. ECG analysis and delivery of the shock are performed manually by the operator.</td>
<td>37806000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Defibrillator for non-medical professionals</td>
<td>An automated or semi-automated defibrillator in which manual mode setting is difficult.</td>
<td>35972020</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Transtelephonic defibrillator</td>
<td>A system that enables a physician to read the electrocardiogram (ECG) for diagnosis and control the defibrillator via a telephone connection at a place distant from the patient. It is composed of a base station (a base where the physician is present) consisting of a portable defibrillator with the function of an electrocardiograph (ECG), a microphone, a battery, a mobile phone (usually cellular phone), a control panel and an ECG display with a recording function.</td>
<td>17579000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Defibrillator for non-medical professionals</td>
<td>An automated or semi-automated defibrillator in which manual mode setting is difficult.</td>
<td>35972020</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Automated peritoneal dialysis system</td>
<td>A device that utilizes automated peritoneal lavage, in which, after dialysis conditions are specified, perfusate is injected intraperitoneally and then allowed to drain.</td>
<td>11226000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Table Heading</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Peritoneal dialysis catheter</td>
<td>A device used to infuse fluid (dialysate) into the peritoneal cavity and utilize the peritoneum as the dialysis membrane. It diffuses metabolic wastes and water out of the blood. Usually, it uses a Dacron cuff, which promotes cell proliferation, for sealing this device to prevent bacterial invasion and fluid leakage. Usually, it is inserted percutaneously for both continuous use and temporary use. It may be surgically implanted or used for a limited period. It is used in manual peritoneal dialysis (continuously performed on an outpatient basis) or automated peritoneal dialysis (continuously and periodically performed), intra-peritoneal chemotherapy or removal of fluid overload resulting from congestive heart failure.</td>
<td>34921000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>Titanium adaptor</td>
<td>An adapter made of titanium. It is used to connect a catheter for peritoneal dialysis to a tube set for peritoneal lavage. An adapter that extends the catheter for peritoneal dialysis is included.</td>
<td>70588000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal dialysis catheterization kit</td>
<td>A package of devices to be used for insertion of a catheter for peritoneal lavage.</td>
<td>16992000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal dialysis tube set</td>
<td>A set of sterile devices intended for peritoneal lavage. The set is for single-use. Usually, the set consists of tubes, a reservoir bag as an option, and appropriate connectors. It may have a peritoneal perfusate filter to capture and remove contaminated substances.</td>
<td>35000000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal dialysis catheter adaptor</td>
<td>A connecting device (usually, it is a small part) that is used to connect a catheter for peritoneal lavage to an external device that manages dialysates. This device is used to connect devices of different makers and makes devices compatible with each other. This device is for single-use.</td>
<td>35944000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable continuous peritoneal dialysis transfer set</td>
<td>A set of devices including tubes to be used in continuous ambulatory peritoneal dialysis (CAPD) that infuses perfusate into and discharges it from the peritoneal cavity.</td>
<td>35986000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Automated peritoneal dialysis unit circuit and related device set</td>
<td>A dedicated device that is attached to an automated peritoneal dialysis system and used for peritoneal dialysis. The dialysis conditions are set in the device, and the infusion, reservoir and drainage of dialysis fluid are repeatedly performed under automatic operation and control.</td>
<td>70590000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal perfusate infusion/drainage tube and related device set</td>
<td>A set of sterile devices used for peritoneal lavage. The set is for single-use. Usually, the set consists of a transfer set for infusion and drainage of peritoneal dialysis fluid, a reservoir bag, and fixing connectors.</td>
<td>70591000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Peritoneal dialysis circuit and related device set</td>
<td>A set of sterile devices used for peritoneal lavage. The set is for single-use. Usually, the set consists of a peritoneal dialysis tube, a reservoir bag as an option, and appropriate connectors.</td>
<td>70592000</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered cardiopulmonary resuscitator</td>
<td>A device that electrically simulates manual closed chest compression, open chest cardiac massage, and artificial respiration to normalize cardiac output and pulmonary ventilation after cardiac arrest or apnea.</td>
<td>35309000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Manually-operated cardiac pump</td>
<td>A device that performs closed chest cardiac massage with manual chest compression to normalize cardiac output after cardiac arrest.</td>
<td>70593000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Mechanical cardiopulmonary resuscitator</td>
<td>A device that simulates manual closed chest compression, open chest cardiac massage, and artificial respiration to normalize cardiac output and pulmonary ventilation after cardiac arrest or apnea. It may use compressed oxygen or air as a drive source.</td>
<td>70594000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Regulatory Code</td>
<td>Approval Level</td>
<td>Approval</td>
<td>Applicable for Remarks</td>
<td></td>
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<tr>
<td>Ascites filtration and reinfusion set</td>
<td>70595009</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ascites filter</td>
<td>70596010</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ascites concentrator</td>
<td>70596020</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood recovery autotransfusion unit</td>
<td>34863003</td>
<td>III</td>
<td>11&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Autotransfusion blood collection unit</td>
<td>36966000</td>
<td>III</td>
<td>11&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Incontinence neuromuscular electrical stimulator</td>
<td>36784000</td>
<td>III</td>
<td>5&lt;sup&gt;-4&lt;/sup&gt;,8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Middle ear implant hearing aid</td>
<td>30084000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Radionuclide system contour detector for remote irradiation therapy</td>
<td>36499000</td>
<td>III</td>
<td>9&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Radionuclide system for remote irradiation therapy</td>
<td>38297000</td>
<td>III</td>
<td>9&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory remote afterloading brachytherapy therapeutic radionuclide system</td>
<td>38300003</td>
<td>III</td>
<td>9&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory manual brachytherapy therapeutic radionuclide system</td>
<td>38299003</td>
<td>III</td>
<td>9&lt;sup&gt;-1&lt;/sup&gt;</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Exempt</td>
<td>Notes</td>
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<tr>
<td>Radionuclide source for remote irradiation therapy</td>
<td>Radiation sources generated in a reactor and used as in a remote afterloading system designed to deliver a therapeutic radiation beam to a target anatomical area. The radiation sources incorporated as a component of the remote afterloading system are generally sealed. The radioisotopes most usually used to remote radiation therapy are cobalt 60 (Co-60), cesium 137 (Cs-137) and iridium 192 (Ir-192).</td>
<td>38305000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-central circulatory remote afterloading brachytherapy therapeutic radionuclide source</td>
<td>A device for the non-central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source used for the after-loading brachytherapy device is provided in various physical configurations – e.g., a single encapsulated radiation source (sealed radiation source), ribbon radiation source, plated, foiled, or embedded radiation source, and encapsulated liquid or gel. The radiation source is contained in a sealed storage container installed in the after-loading device, and transferred to the treatment site via guide tube in various structures.</td>
<td>38302003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-central circulatory permanent implant manual brachytherapy therapeutic radionuclide source</td>
<td>A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be permanently implanted in the body for radiation therapy requiring treatment or symptomatic treatment. In general, the device is placed in the body using an applicator with the assistance of a fluoroscope or an endoscope. The radiation source for manual permanent implantation is designed so that histocompatibility can be achieved. Morphological types of radiation sources include microsphere, sphere, stent, seed, and wire, which are used to generate low-energy photons, beta particles, or alpha particles.</td>
<td>38303003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-central circulatory temporary placement manual brachytherapy therapeutic radionuclide source</td>
<td>A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be temporarily implanted in the body and to be removed after a prescribed duration of treatment. Used in brachytherapy, the device is placed and removed manually or under endoscopic observation. Radiation sources to be placed manually for temporary implantation are provided in a variety of forms, including encapsulated, sealed, plated, foiled, and embedded. Some devices may be directly inserted into the body, and others may be implanted using a catheter or an applicator. Morphological types of radiation sources include needle, sphere, ovoid, seed, wire, and fluid filled in a cuff of a catheter.</td>
<td>38304003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Radionuclide system for Stereotactic radiotherapy</td>
<td>A device for delivering a therapeutic dose from external beams to an anatomical area. The external beams are generated with multiple radiation sources collimated and arranged to reach one specified focus. The standard equipment configuration is as follows: 1. a stereotactic positioning device attached to the patient for determination of the 3D coordinates of the anatomical area to be treated, 2. a set of a helmet with a fixed diameter and a collimator, 3. a high-density plug that is attached to the hole of the helmet to function as a beam breaker, 4. a shielded hole to store the radiation sources and reduce radiation in the room, 5. radiation sources precisely arranged so that beams from all radiation sources cross at a single point, 6. a movable patient table.</td>
<td>38298000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Radionuclide source for Stereotactic radiosurgery therapeutic</td>
<td>A radioisotopes generated in a reactor and used as one of a series of radiation sources incorporated into a stereotactic radiosurgery system designed to deliver precisely focused radiation beams required in symptomatic or other treatment to a target anatomical area. The radiation source used in a stereotactic radiosurgery system is generally sealed (sealed radiation source). Different from other therapeutic radiation sources, multiple radiation sources are used in a stereotactic radiosurgery system. And multiple external radiation beams which are focused and fixed on a single point are simultaneously generated. The radioisotope most commonly used for stereotactic radiosurgery is cobalt 60 (Co-60).</td>
<td>38306000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for vaginal manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various vaginal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38406000</td>
<td>III</td>
<td>7-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for vaginal remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the vagina. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38407000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for manual cervical/endometrial brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for uterine cervix or intrauterine radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, placement with an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various uterine cervical or endometrial applicators including hollow needles, tubes, and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38408000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for brachytherapy Cervical/endometrial remote afterloading</td>
<td>A remote controlled brachytherapy applicator specifically designed for uterine cervix or intrauterine radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the uterine cervix and endometrium. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38409000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for bronchial manual brachytherapy applicator</td>
<td>A manual brachytherapy applicator specifically designed for temporarily use in bronchial radiation therapy. A single or module applicator designed to facilitate manual placement (placement using an endoscope or positioning, placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various bronchial applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38410000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for bronchial remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for bronchial radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the bronchus. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38411000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
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<tr>
<td>Applicator for nasopharynx manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the nasopharynx. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various nasopharyngeal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38414000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for nasopharynx remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the nasopharynx. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38415000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for tongue manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for lingual radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the tongue and the surrounding tissues. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various lingual applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38416000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for tongue remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for tongue or oral cavity radiation therapy. It is designed to be temporarily implanted in the tongue or the surrounding tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38417000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for neck manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for neck radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the neck tissues. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various neck applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38418000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for neck remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for neck radiation therapy. It is designed to be temporarily implanted in the neck tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38419000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for esophagus manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for esophagus radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the esophagus. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various esophageal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38420000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
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<tr>
<td>Applicator for esophagus remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for esophagus radiation therapy. It is designed to be temporarily implanted in the esophagus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38421000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for bile duct manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for bile duct radiation therapy. An applicator designed to have a configuration that facilitates manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bile duct. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various bile duct applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38422000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for brachytherapy bile duct remote afterloading</td>
<td>A remote controlled brachytherapy applicator specifically designed for bile duct radiation therapy. It is designed to be temporarily implanted in the bile duct. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites. This device group contains hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38423000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for pancreas manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for pancreatic radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement, or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the pancreas. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various pancreatic applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38424000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for pancreas remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for pancreatic radiation therapy. It is designed to be temporarily implanted in the pancreas. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38425000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for prostate manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for prostate radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement or removal with a trigger loading device, an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the prostate gland. It may be designed to be standard in configuration or to handle specific radiation sources. It contains various prostate applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38426000</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>category</td>
<td>DA Code</td>
<td>FSA Code</td>
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<tr>
<td>Applicator for prostate remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for prostate radiation therapy. It is designed to be temporarily implanted in the prostate gland. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38427000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for bladder manual brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for bladder radiation therapy. An applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bladder. It may be designed to be standard in configuration or to handle specific radiation sources. It contains bladder applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38428000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for bladder remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for bladder radiation therapy. It is designed to be temporarily implanted in the bladder. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38429000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for manual rectal/anal brachytherapy</td>
<td>A manual brachytherapy applicator specifically designed for rectal and/or anal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the rectum and/or anus. It may be designed to be standard in configuration or to handle specific radiation sources. It contains rectal or anal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.</td>
<td>38430000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for rectal/anal remote afterloading brachytherapy</td>
<td>A remote controlled brachytherapy applicator specifically designed for rectal or anal radiation therapy. It is designed to be temporarily implanted in the rectum or anus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>38431000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for eye manual brachytherapy</td>
<td>A template with a groove on the one side. The groove shows the position of the brachytherapy source that is manually, temporarily delivered to the eye surface. The other side is shielded.</td>
<td>38434000</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
</tr>
<tr>
<td>Applicator for brachytherapy non-central circulatory general-purpose manual</td>
<td>A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy, and placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the non-central circulatory system. Some are designed in a standard configuration, and others are designed in various physical configurations, or designed so as to be easily processed into a configuration that can handle specific radiation sources. It comes in hollow needles, tubes, catheters, ovoid, and tandem.</td>
<td>38435003</td>
<td>III</td>
<td>7-3</td>
<td>applicable</td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>Classification</td>
<td>Applicable</td>
<td>Applicable</td>
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<tr>
<td>Applicator for brachytherapy non-central circulatory general-purpose remote afterloading</td>
<td>A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the non-central circulatory system. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.</td>
<td>III</td>
<td>7-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Stereotactic radiotherapy accelerator system</td>
<td>A stereotactic radiation therapy system for treatment based on a linear accelerator (or microtron). Output is limited to a narrow, high-energy beam. The gantry allows radiation from a wide range of angles and positions. The device may be used to inactivate lymphocytes.</td>
<td>18054000</td>
<td>9-①</td>
<td>applicable</td>
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</tr>
<tr>
<td>Linear accelerator system</td>
<td>A treatment system capable of producing high-energy electrons, which can produce high-energy X-rays (or electron beams). The system provides a radiation field of uniform intensity and predictable energy level in a beam with well-defined dimensions. The operating principle is linear acceleration of electrons by means of microwaves. The output is used as therapeutic beam, either directly or after allowing it to pass through a suitable target. The system is often used in the treatment of cancer. The device may be used to inactivate lymphocytes.</td>
<td>35159000</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>X-ray/CT combined linear accelerator system</td>
<td>A combined system of a linear accelerator system and an X-ray CT system for radiotherapy planning.</td>
<td>70602000</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-linear accelerator system</td>
<td>A therapeutic particle accelerator system using a strong magnetic field to produce a non-linear acceleration path for particles accelerated in an alternating electric field. The acceleration path is mostly spiral or circular. The output is used as therapeutic beam, either directly or after allowing it to pass through a suitable target. The device may be used to inactivate lymphocytes.</td>
<td>33073000</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Particle radiotherapy equipment</td>
<td>A system that generates a high energy beam consisting of particles including protons, neutrons and carbon ions and radiates this particle beam to deliver the therapeutic dose to the affected area. It is mainly used in cancer treatment. It consists of an accelerator which accelerates the main particles to high energies, an irradiation nozzle which forms the beam (output of the high energy) and radiates it to a patient, and a device which very precisely locates the affected area. Generally, it is equipped with an ion source, an accelerator, a rotary or fixed gantry, a positioning device, a movable table, an operator console, etc.</td>
<td>70603010</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Living tissue radiotherapy system</td>
<td>A low energy X-ray therapy system designed to treat adjacent tumor lesions with high dose X-rays by placing soft X-ray beams from 5 to 50 kV inside the tumor tissue. The energy range of these X-ray beams are higher in the Grenz Ray therapy system and lower in the orthovoltage X-ray treatment system. It is not used for superficial skin tumors for which a low voltage X-ray therapy system is indicated. It is used in both intraoperative radiation and stereotactic localized radiation therapy. The former is performed for residual tumor after surgical resection of the neoplasm. In the latter, interstitial radiation is performed after diagnosis of tumor tissues obtained by biopsy.</td>
<td>70604000</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>X-ray/CT combined particle radiotherapy equipment</td>
<td>A combined system of particle radiotherapy equipment and an X-ray CT system for radiotherapy planning.</td>
<td>70603020</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Detailed Description</td>
<td>Code</td>
<td>Type</td>
<td>Category</td>
<td>Applicability</td>
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<tr>
<td>Radiation therapy simulator</td>
<td>Special configuration of a diagnostic radiography system used for radiation treatment planning, consisting of a fluoroscope, a radiographic device, and associated hardware and software. It is used to determine the radiation field size and position based on a generated series of parameters. The system may include equipment for signal analysis and display, and supporting apparatus relevant to the patient and other equipment. Generally, measured parameters are received and transmitted to the radiation treatment planning system to be used for therapeutic calculations.</td>
<td>35294000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>X-ray CT system for radiotherapy planning</td>
<td>A X-ray CT system that has a special configuration, containing hardware, software, etc. used in radiotherapy planning. It is used to determine the size and positioning of the therapeutic radiation field based on a series of treatment parameters to be generated. It may contain a device for signal analysis and display, a supporting device for the patient and the system and a device for moving the patient and the system. Generally, it receives measured parameters and sends the data to the radiotherapy planning system for therapeutic calculation.</td>
<td>70605000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Motorized automatic aperture control accelerator system collimator</td>
<td>A beam control device with a motor. It is a collimator assembly. The function to adjust the jaw or leaf positioning is controlled by computer. It is placed in the beam projection port of the accelerator housing and used to adjust the form of the radiation beam that is delivered to the therapeutic target area of the body. It is made of a highly attenuating material or alloy including lead and tungsten, and protects patients by controlling or avoiding delivery of radiation to non-target areas of the body. Usually, the collimator is designed to contain a light localizer that displays the position of the radiation beam and helps to adjust the position of the patient to be treated.</td>
<td>38138000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Psychiatric therapy brain electrical stimulator</td>
<td>A type of stimulator that stimulates a specific area (e.g., cerebrum, cerebellum) of a patient undergoing psychotherapy. Usually, it consists of an external pulse generator and electrodes. Stimulation pulses are provided via the electrode array placed in the cortex or the electrode tip with a very thin lead, implanted in the deep cerebellar nucleus. It is used for treatment of psychological disorders (e.g., depression, anxiety, mania, and insomnia).</td>
<td>36164000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Convulsive therapy brain electrical stimulator</td>
<td>A device that treats depression by inducing a convulsion (a seizure) with an electric current applied to the brain via externally placed electrodes.</td>
<td>11484000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Helium/neon laser</td>
<td>A gas laser used in surgical procedures, etc. It utilizes a mixed gas of helium (He) and neon (Ne) as the substrate. Visualization of beams is easy. Therefore, it is used as a beam for sighting or positioning the target (pilot/lead beam).</td>
<td>36531010</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Helium/neon laser therapy equipment</td>
<td>A gas laser used in treatment for remission of pain resulting from chronic, noninfectious inflammation of the muscle or joint or in treatment of hyperesthesia. It uses a mixed gas of helium and neon as the substrate.</td>
<td>36531020</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Semiconductor laser therapy equipment</td>
<td>A semiconductor laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths and pain remission treatment. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate. A semiconductor laser used in pain remission treatment and photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate.</td>
<td>70630000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>PDT excimer laser</td>
<td>An excimer laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes an excited dimer as the active substance.</td>
<td>35984020</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Laser Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Applicable</td>
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<tr>
<td>Alexandrite laser</td>
<td>A laser that is used in surgical procedures and utilizes alexandrite as the substrate.</td>
<td>70631000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>PDT semiconductor laser</td>
<td>A semiconductor laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate.</td>
<td>70632000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Carbon dioxide laser</td>
<td>A gas laser that is used in surgical procedures. It utilizes carbon dioxide as the substrate. It is widely used in several clinical fields (e.g., gynecology, neuroscience, dermatology).</td>
<td>35939000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Nd:YAG laser</td>
<td>A laser that is used for surgical procedures. It utilizes a crystal consisting of neodymium (Nd), and yttrium, aluminum and garnet (YAG) as the substrate. It is widely used in peritoneoscopic and endoscopic procedures. A special type of device is used in ophthalmology.</td>
<td>35940000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Nd:YAG doubled frequency laser</td>
<td>A type of double frequency laser. Usually, it is operated in continuous mode or pulse mode and used in surgical procedures which require precise resection, evaporation and photococagulation with minimal damage to the surrounding tissue. It utilizes a crystal consisting of neodymium (Nd), and yttrium, aluminum and garnet (YAG) as the substrate. The tissue interaction in the surgical site is determined by the power density selected for the specific use.</td>
<td>36150000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Erbium:YAG laser</td>
<td>A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of erbium, and yttrium, aluminum and garnet (YAG) as the substrate.</td>
<td>36169000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Holmium:YAG laser</td>
<td>A laser that is used in surgical procedures, etc. and utilizes a crystal consisting of holmium, and yttrium, aluminum and garnet (YAG) as the substrate. It is used in peritoneoscopic and endoscopic procedures.</td>
<td>36170010</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Pulsed holmium:YAG laser</td>
<td>A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of holmium (Ho), and yttrium, aluminum and garnet (YAG) as the substrate.</td>
<td>36170020</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Argon laser</td>
<td>A gas laser that is used for surgical procedures, etc. and utilizes argon gas as the substrate. It is used in some clinical fields (e.g., neuroscience, otology, ophthalmology).</td>
<td>35938000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Diode laser</td>
<td>A laser that is used in surgical procedures etc. It utilizes a solid state substance (e.g., gallium arsenide) as the substrate. It may be used in ophthalmology, etc.</td>
<td>36546000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use laser guide contact probe</td>
<td>A device dedicated for use with a laser. This device is for single-use. It is used to deliver the laser output energy for the ultimate target area (e.g., surgical area). It is made of flexible optical fibers and the operator can move and induce it easily. Usually, it is connected to a laser delivery device.</td>
<td>17193000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Excimer laser</td>
<td>A gas laser that is used in surgical procedures, etc. and utilizes an excited dimer (EXCItedDiMER) as the substrate. The substrate most commonly used is a noble gas halide (e.g., argon fluoride, xenon chloride).</td>
<td>35984010</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dye laser</td>
<td>A liquid laser that is used in surgical procedures, etc. and utilizes an organic compound (pigment) with a strong absorption band as the active medium. In luminescence, the pigment is required to be optically excited by another light source (e.g., another laser, flash lamp).</td>
<td>36043000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Carbon monoxide laser</td>
<td>A gas laser that is used in surgical procedures, etc. It utilizes carbon monoxide as the substrate.</td>
<td>36168000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
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<tr>
<td>Argon/krypton laser</td>
<td>A gas laser that is used in surgical procedures, etc. It utilizes argon krypton gas as the substrate. It is used in ophthalmology, etc.</td>
<td>36171000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ruby laser</td>
<td>A laser that utilizes ruby as the substrate. It is used in dermatology, etc.</td>
<td>36189000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Laser delivery unit waveguide</td>
<td>A device consisting of a rigid hollow tube with multiple connections that can be flexed freely. Through this device, laser energy generated from the laser output source is transmitted to near the target area. Usually, it is used with an infrared laser. To deliver laser beams ultimately to the target area, a laser fiber probe that is for single-use can be connected. A refractor system is employed in the joint so that laser beams can be refracted while passing through the device.</td>
<td>36203000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Copper vapour laser</td>
<td>A gas laser used in surgical procedures, etc. It utilizes copper vapor as the substrate. It is used in dermatology, etc. for treatment of cutaneous vascular lesions (e.g., port-wine stains, telangiectasia).</td>
<td>36238000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Endotherapy laser guide</td>
<td>A dedicated device used with an endoscope in endoscopic therapy. It is used to guide or direct a laser beam during endoscopic laser treatment. Usually, it is made of quartz fibers and connected to the laser power supply arm.</td>
<td>36288000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dye/alexandrite laser</td>
<td>A liquid laser used in surgical procedures, etc. It utilizes dye and alexandrite as the substrate.</td>
<td>36301000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Krypton laser</td>
<td>A gas laser that utilizes krypton (Kr) as the substrate.</td>
<td>36532000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Helium/cadmium laser</td>
<td>A gas laser used in surgical procedures, etc. It utilizes a mixed gas of helium (He) and cadmium (Cd) as the substrate.</td>
<td>37051000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>KTP laser</td>
<td>A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of potassium, titanium and phosphoric acid (KTP) as the substrate. An infrared beam (YAG) generated from the neodymium:yttrium, aluminum and garnet source pass the KTP crystal and some of the infrared light is converted into visible light at the green end of the spectrum. It is used in some clinical fields (e.g., neuroscience, otology, ophthalmology, dermatology).</td>
<td>37202000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic PDT laser system</td>
<td>An ophthalmic laser system used in combination with a photosensitizer in photodynamic therapy. For instance, it is used in treatment of age-related macular degeneration.</td>
<td>70633000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic laser photoagulation system</td>
<td>A device used for the treatment of eye diseases, utilizing the thermal effect of lasers. For instance, the device may be used for photoagulation of the retina, iris, ciliary body, or chamber angle.</td>
<td>70634000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic pulsed laser surgical system</td>
<td>A device used for the treatment of eye diseases or incision of eye tissue, utilizing the destructive or thermal effect of the pulsed laser-induced shock-waves. For example, the device may be used for posterior capsulotomy or photoagulation of the iris or chamber angle.</td>
<td>70635000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic laser photoagulation/pulsed laser surgery system</td>
<td>A composite system consisting of an ophthalmic laser photoagulation system and an ophthalmic pulse laser surgical system.</td>
<td>70636000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Excimer laser angioplasty unit</td>
<td>A gas laser that is used in percutaneous transluminal angioplasty. It utilizes an excited dimer (EXCIteddiMER) as the substrate. The substrate most commonly used is a noble gas halide (e.g., argon fluoride, xenon chloride).</td>
<td>70637000</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable?</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Ophthalmic corneal surgery laser system</td>
<td>A device that utilizes the ablation function of the laser and used in keratectomy. For instance, it is used in corneal surface resection, corneal refractive surgery, etc.</td>
<td>70638000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic laser photocoagulation system probe</td>
<td>A probe-type delivery system designed to be used after connection to a laser photocoagulation system. Some devices are capable of illumination or suction. The device may be for single-use or reusable.</td>
<td>70639000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic laser photocoagulation system sterile probe</td>
<td>A probe-shaped delivery system to be connected to an ophthalmologic laser photocoagulation system before use. It may have an illumination function or the aspiration function. This device is sterile and for single-use.</td>
<td>70640000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Fibreoptic laser delivery unit</td>
<td>A flexible optical fiber cable used to provide visible and near-infrared wavelength laser energies. With this device, the laser output source is transmitted to near the target area. To deliver laser beams ultimately to the target area, a laser fiber probe that is for single-use can be connected.</td>
<td>36185000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Skin laser scanner</td>
<td>A device that scans a wide area uniformly with a laser beam generated from an appropriate laser. A laser beam is focused intensively on a very small lesion at each scanning. Therefore, in order to treat a wide area, a scanner should be used to deliver the laser beam back and forth to scan the entire target area. This device is used for removal of nevi, pigmentation, tattoos, etc.</td>
<td>36775000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Laser delivery unit holder</td>
<td>A device used in conjunction with a laser delivery device. This device supports the laser delivery device when the laser is operated. It supports positioning of the final output of laser beam, prevents unwanted movement and improves safety.</td>
<td>41707000</td>
<td>III</td>
<td>9-2</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental hard/soft tissue ablation laser</td>
<td>A dental device with the function of a carbon dioxide laser or Er:YAG laser part as well as that of a tooth surface cleaner to remove carbonized tooth substance. It is used for vaporization/resection of oral cavity soft tissues and for coagulation/ carbonization of the affected dentin (only C2).</td>
<td>70641000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable laser contact tip</td>
<td>A reusable solid tip. A laser passes through the tip and is converted into heat on the tissue. Usually, the tip is used in contact with the tissue.</td>
<td>70642000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable laser delivery unit handpiece</td>
<td>A reusable handpiece that is connected to an optical fiber or a waveguide of a laser delivery device and used. Usually, it is used held in hand.</td>
<td>70643000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose electrosurgical unit</td>
<td>A unit used to resect/ablate the tissue or to coagulate the incision/wound site with high-frequency waves. The high-frequency waves are emitted between the active and neutral electrodes or between two active electrodes and applied to the patient’s body. The thermal effects associated with tissue destruction in electrosurgery are generated by the resistance of the tissue to high-frequency or high-dense waves rather than that to heat as in electrocautery. This treatment method is usually known as surgical diathermy.</td>
<td>11490000</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrosurgical system electrode with return alarm</td>
<td>A conductor that establishes an electrical connection between the output terminal of the generator of an electrosurgical unit and the patient who receives the electrosurgical effect. (It may be used with cables. ) It is fixed to the patient’s body. (Usually, it is positioned in such a way that the contact of made with the entire plate is the most appropriate for the specific procedure. )</td>
<td>11500013</td>
<td>III</td>
<td>9-1</td>
<td>applicable</td>
</tr>
</tbody>
</table>

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<p>| <strong>Electrosurgical patient plate</strong> | An electrode with a relatively wide surface area used to make current density in the high-frequency return circuit low enough to avoid damage to living tissue, such as burns. It is closely attached to the patient body when used. It has a relatively larger surface area than an operational return electrode. It contains electrodes, conductive cords, and their related accessories. It is used with a therapeutic electrosurgical unit and an active therapeutic device. | 11500023 | III | 9-① | applicable | N/A |
| <strong>Electrosurgical system with electrode disconnection alarm</strong> | A device used with an electrosurgical unit for detection of blockage of the return electrode cable between the electrosurgical unit and the return electrode (an electrode suspected of electric current leakage). This device functions as a special type of patient circuit safety monitor and gives a warning if any safety limit is exceeded. This function is pre-incorporated in the latest electrosurgical units. Therefore, this device may reflect conventional techniques. | 35632000 | III | 9-① | applicable | applicable |
| <strong>Argon gas delivery electrosurgical unit</strong> | A unit that provides argon gas for an electrosurgical unit. The argon gas is provided via the active electrode of the electrocautery attached to the unit and forms the protective layer to prevent oxidation around the surgical site during incision and coagulation, which keeps the tissue surface clean. This device is installed in the mount and connected to the electrosurgical unit. Thereby, both the device and unit can be integrally operated. | 36154000 | III | 9-① | applicable | applicable |
| <strong>Argon-enhanced electrosurgical unit</strong> | A monopolar electrosurgical unit (ESU) equipped with a certain system (usually, it is housed in an individual transfer trolley or incorporated in the generator chassis of the ESU) for providing argon gas. The electrosurgical current forms the ionized channel (arch) which reduces tissue carbonization and coagulates a large bleeding surface (e.g., capillary bed) rapidly and uniformly. This method is also called surgical diathermy. | 36155000 | III | 9-① | applicable | applicable |
| <strong>Mechanical vibration electrosurgical unit</strong> | An electrosurgical unit used for ablation and coagulation of the soft tissues of the body with a high-frequency current during surgery. The high-frequency energy is converted to mechanical vibrations of the two blade edges at the tip of the ablation device. These blade edges vibrate with a high-frequency mechanical movement, ablate and fracture collagen molecules in the tissue. Thereby, vibration and degeneration of collagen occur resulting in coagulation. This mechanical movement can be generated with ultrasonic as an energy source. | 36273000 | III | 9-① | applicable | applicable |
| <strong>Radio-frequency ablation system</strong> | A system that heats and cauterizes malignant or benign tumors, etc. with radio wave energy. | 36070000 | III | 9-① | applicable | applicable |
| <strong>Percutaneous cardiac coagulation/ablation electrosurgical unit</strong> | A unit used to percutaneously cauterize/coagulate the cardiac muscle/myocardial tissue with high-frequency waves. It is used with catheter electrodes. The high-frequency waves are emitted between the active and neutral electrodes. | 70644000 | III | 9-① | applicable | applicable |
| <strong>Electrosurgical unit for cardiac ablation</strong> | A unit for percutaneously cauterize/coagulate the cardiac muscle/myocardial tissue with high-frequency waves. It is used with a probe. The high-frequency waves are emitted between the active and neutral electrodes. The thermic effects associated with tissue destruction in electrosurgery are provided by the resistance of the tissue to high-frequency or high-dense waves rather than that to heat as in electrocautery. | 70645000 | III | 9-① | applicable | applicable |
| <strong>Cauterization probe</strong> | A probe that is connected to an ablation electrosurgery unit and used to cauterize/coagulate the tissue. | 70646000 | III | 9-① | applicable | — |
| <strong>Non-visual non-endoscopic electrosurgical unit</strong> | A base unit and its related accessories that perform incision and coagulation of the tissue with high-frequency current non-visually and non-endoscopically. | 70648000 | III | 9-① | applicable | applicable |</p>
<table>
<thead>
<tr>
<th>Product Description</th>
<th>Material Code</th>
<th>Class</th>
<th>Approval Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material combined electrosurgical unit</td>
<td>70649000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Battery-powered electrosurgical cautery unit</td>
<td>35029000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Line-powered cautery</td>
<td>35030000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Ophthalmic electrosurgical unit</td>
<td>41645000</td>
<td>III</td>
<td>9-①</td>
<td>applicable N/A</td>
</tr>
<tr>
<td>Phacoemulsification cataract extraction unit</td>
<td>17596000</td>
<td>III</td>
<td>6-③</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Microwave surgical unit</td>
<td>70650000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Ultrasonic knife handpiece</td>
<td>39837000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Ultrasonic knife unit</td>
<td>36540000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Ultrasonic suction system</td>
<td>37776000</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Ultrasonic surgical unit</td>
<td>70651000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Cataract/vitreous surgical unit</td>
<td>70652000</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
</tbody>
</table>

70649000 III 9-① applicable applicable

70650000 III 9-① applicable applicable

70651000 III 9-① applicable applicable

70652000 III 9-① applicable applicable
<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Description</th>
<th>Classification</th>
<th>Applicable</th>
<th>Reusable</th>
</tr>
</thead>
<tbody>
<tr>
<td>General-purpose cryosurgical unit</td>
<td>A unit supplying refrigerant gas or liquid for heat dissipation in the target tissue, either by direct supply of refrigerant or indirectly by contact of a probe cooled with refrigerant. The device is usually used for general surgical treatment (e.g., dermatology, oral cavity surgery, gynecology, urology, otolaryngology, and proctology).</td>
<td>11067000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Ophthalmic cryosurgical unit</td>
<td>An ophthalmic surgical device for cataract extraction and other ophthalmic surgery to cool the target tissue by means of applying gas or liquid refrigerant either directly or indirectly by contact of a cryogenic probe.</td>
<td>11068000</td>
<td>III</td>
<td>6-③</td>
</tr>
<tr>
<td>Single-use hand-controlled electrosurgical unit active electrode</td>
<td>A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is the main part of the electrode and can be operated manually by an operator. Usually, it is in the shape of a pen or pencil and often referred to by either one of these names. This device is for single-use.</td>
<td>35044000</td>
<td>III</td>
<td>9-②</td>
</tr>
<tr>
<td>Single-use foot-controlled electrosurgical unit active electrode</td>
<td>A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is incorporated into the foot pedal. The ablation mechanism can be adjusted by operating the pedal. Usually, it is in the shape of a pen, a pencil, scissors, a knife or forceps and often referred to by one of these names. This device is for single-use.</td>
<td>70656000</td>
<td>III</td>
<td>9-②</td>
</tr>
<tr>
<td>Reusable hand-controlled electrosurgical unit active electrode</td>
<td>A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is the main part of the electrode and can be operated manually by the surgeon. Usually, it is in the shape of a pen or pencil and often referred to by either one of these names. This device is reusable.</td>
<td>42552000</td>
<td>III</td>
<td>9-②</td>
</tr>
<tr>
<td>Reusable foot-controlled electrosurgical unit active electrode</td>
<td>A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is incorporated into a foot pedal. The ablation mechanism can be adjusted by operating the pedal. Usually, it is designed in the shape of a pen, a pencil, scissors, a knife or forceps. It is often referred by one of these names. This device is reusable.</td>
<td>42553000</td>
<td>III</td>
<td>9-②</td>
</tr>
<tr>
<td>Driving unit for angioplasty athectomy catheter</td>
<td>A drive unit (a rotablator) used to remove hardened, calcified atherosclerotic plaques from the arterial wall percutaneously and transluminally.</td>
<td>70659000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Hair root electrolyser</td>
<td>A device that destroys the hair roots by electrolysis. For instance, it is used in the treatment of ingrowing eyelashes.</td>
<td>70660000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Diathermy unit</td>
<td>A composite apparatus of an ophthalmic electrosurgical unit and a hair root electrolyser.</td>
<td>70661000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Laser procedure active instrument</td>
<td>A probe, light-guiding fibers, conductive cords, and their related accessories. They are used for incision and coagulation of the tissue with a laser.</td>
<td>70663000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Ultrasound procedure active instrument</td>
<td>A probe, conductive cords, and their related accessories. They are used for incision, coagulation, and fragmentation of the tissue with ultrasound.</td>
<td>70664000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Description</td>
<td>Active electrodes, conductive cords and their related accessories. They are used for incision and coagulation of the tissue non-visually and non-endoscopically with a high-frequency electric current.</td>
<td>Code</td>
<td>Category</td>
<td>Applicability</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Non-visual non-endoscopic procedure active instrument</td>
<td>70665000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Therapeutic active instrument</td>
<td>70666000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Multiple energy sources active instrument</td>
<td>70667000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Material-combined procedure active instrument</td>
<td>70668000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>High-frequency current procedure active instrument with automatic function</td>
<td>70669000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrosurgical unit with automatic function</td>
<td>70670000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Therapeutic electrosurgical unit</td>
<td>70671000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Radio-frequency lesion probe</td>
<td>A device that is connected to a radio frequency (RF) lesion generator and provides RF energy for a specific site in the nervous system where a therapeutic lesion is to be generated.</td>
<td>32531000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Radio-frequency lesion generator</td>
<td>A device that administers a high-frequency electric current (radio frequency) to the internal nerves in order to increase temperature in a controlled way to create a therapeutic lesion. A dedicated probe equipped with an electrode and a temperature sensing element at the tip is connected to this device, and energy is provided to the site to be treated. It may be used in sensitive sites including those in the brain.</td>
<td>35156000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Microwave hyperthermia system</td>
<td>A system used to generate high temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled, and heats the whole body or heats tissues or internal organs in a localized manner using a microwave energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator separately inserted into the local site endoscopically or surgically.</td>
<td>40783000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>High-frequency hyperthermia system</td>
<td>A system used to generate high-temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and heats the whole body or heats tissues or internal organs in a localized manner using a radio-frequency wave (RF) energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator separately inserted into the local site endoscopically or surgically.</td>
<td>40782000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Ultrasound hyperthermia system</td>
<td>A system used to generate high-temperatures (higher than 43°C) and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and it heats the whole body or tissues or internal organs in a localized manner using an ultrasonic energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator inserted into a local site endoscopically or surgically.</td>
<td>40781000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Heated fluid hyperthermia system</td>
<td>A system that generates high-temperature fluids and controls fluid circulation in the vest, mattress, jacket, band, pad, bodywrap, catheter probe and other parts of the system in order to generate heating effects over the whole body or at localized sites in the treatment of malignant and benign tumors or other diseases. Usually, it is computer-controlled and used to perform radical or palliative treatment by increasing the temperature to 43°C or higher over the whole body, or to localized tissues or organs in a controlled way while controlling the effects on the non-target tissues.</td>
<td>40784000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Laser hyperthermia system</td>
<td>A system that heats the targeted living tissue to a high temperature in order to treat malignant or benign tumors and other diseases. The system heats the whole body or tissues and internal organs in a localized manner with laser light energy. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe type applicator separately inserted into the local site endoscopically or surgically.</td>
<td>70672000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Combination hyperthermia system</td>
<td>A system used to generate high temperatures (higher than 43°C) and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and heats the whole body or tissues or internal organs in a localized manner using 2 or more energy sources (or individually) including ultrasonic, radio-frequency (RF) wave and microwave sources, and the heated circulating liquid. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator inserted into the local site endoscopically or surgically.</td>
<td>40785000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Intracorporeal shock wave lithotripter</td>
<td>A lithotripter that is used in combination with a pyeloscope or an ureteroscope and has a probe. The handpiece consists of a shock wave source and a steel probe. A shock wave source consists of a projectile accelerated by the energy source (e.g., compressed air, electromagnetic coils). The shock wave is transmitted to the steel probe through a collision between the projectile and the steel probe, and a stone is fragmented by the mechanical vibration. The devices corresponding to an intracorporeal laser lithotripter, an intracorporeal ultrasonic lithotripter, and an intracorporeal electrohydraulic lithotripter are excluded.</td>
<td>70673000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Intracorporeal laser lithotripter</td>
<td>A system consisting of a special ureteroscope, a laser-resistant catheter, a dedicated laser (presently, dye laser with a green light), etc. It is used to fragment a ureteral stone. The calculus is irradiated with laser energy to fragment it. Then, the fragmented calculi are removed forcibly or eliminated spontaneously.</td>
<td>36037000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Intracorporeal ultrasonic lithotripter</td>
<td>A system consisting of rigid tubular devices including an operating sheath, a pyeloscope or ureterorenoscope, and an ultrasonic lithotripsy probe. The lithotripsy probe consists of an ultrasonic transducer and a steel probe. The ultrasonic transducer converts sound waves to horizontal and vertical vibrations. These vibrations are transmitted along the hollow probe contacted with the stone, which is fragmented by the mechanical vibrations. The probe can be connected to a suction pump, and fragmented calculus are sucked through the lumen of the probe.</td>
<td>35712000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Device Description</td>
<td>Notes</td>
<td>Code</td>
<td>Class</td>
<td>Number</td>
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</tr>
<tr>
<td>Intracorporeal electrohydraulic lithotripter</td>
<td>A device that fragments a stone located in the kidney, ureter, bladder, or bile duct utilizing plasma-induced shock waves. Usually, it consists of a generator-driven probe that emits energy pulses to the center of the calculus while circulating saline solution in a probe. The impact of water pressure (the shock wave occurring when the bubble bursts), which is produced by the plasma bubble generated, fragments the calculus into a number of pieces. The fragments are removed with surgical devices (e.g., a grasper, stone basket).</td>
<td>35711000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Ballistic lithotripter</td>
<td>A device that generates shock waves with the air-compressed tip operated continuously and fragments the targeted stone.</td>
<td>70674000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Micro-explosive shock wave lithotripter</td>
<td>A device equipped with a pin hammer for lithotripsy at the tip of the insertion part of the device. It operates the pin hammer by the explosion of a minute amount of powder loaded at the rear end of the insertion part, and fragments a stone.</td>
<td>70675000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Single-use intracorporeal lithotripsy ultrasound transducer assembly</td>
<td>A transducer assembly enclosed in a catheter designed to be inserted into the body via a blood vessel, surgically or endoscopically in order to perform local lithotripsy (fragmentation of a stone). It consists of a single or multiple transducer element array(s) (also called a piezoelectric element, active element, or crystal element), attenuation materials, relining materials, and matching materials.</td>
<td>44138000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Renal water jet catheter system</td>
<td>A system used to remove a stone from the depth of the renal pelvis by water injection under pressure through a catheter. It is used to remove a renal calculus surgically.</td>
<td>32070000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Intracorporeal puncture lithotripter</td>
<td>A device equipped with a drill for lithotripsy at the tip of the device. With the drill, it makes a hole in a stone and implements perforation and fragmentation of the stone. Usually, the drill for lithotripsy is passed through a rigid endoscope inserted into the body and introduced to a vesical or ureteral stone and makes a perforation that allows the stone to be fragmented through rotation of the drill. The drilling part is thin and long, but it does not oscillate with the rotation. The drill can be changed according to the form and hardness of the stone. The fragments are removed forcibly or eliminated spontaneously later.</td>
<td>70676000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Fluoroscopic X-ray intracorporeal lithotripter</td>
<td>A device equipped with a pin hammer for lithotripsy at the tip of the part inserted into the body. It fragments a stone with a shock delivered by the protrusion of the pin hammer. Usually, the pin hammer-shaped operating part is passed through a rigid endoscope which is inserted via the urethra under lumbar anesthesia and introduced to the stone in the urethra. Then, the pin hammer-shaped operating part is activated, and the pin hammer is protruded and fragments the stone. The operating part is introduced and operated under fluoroscopy. The operating part is internally loaded with a minute amount of powder. The pin hammer is protruded by the explosion of the powder, and the stone is fragmented by the shock. The fragmented stones are eliminated from the body during urination.</td>
<td>70677000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Extracorporeal lithotripter</td>
<td>A device that sends noninvasive shock waves extracorporeally to fragment and pulverize a stone internally produced. This technique is called extracorporeal shock wave lithotripsy (ESWL). The methods employed by the device include a method using submersible electrodes (to emit shock waves that target a stone) or a method using a cylinder containing pressurized water, etc. and a shock wave generator (to use shock waves focused on pulverizing a stone). Usually, the cylinder is positioned so as to be protruded from a cushioned treatment table that touches the patient skin. The sand-like fragments produced are eliminated from the body through natural excretion.</td>
<td>36032000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Atmocautery</td>
<td>A device used for hemostasis by supplying of superheated steam directly to a vessel. Usually, it is used for non-malignant uterine lesions.</td>
<td>34862000</td>
<td>III</td>
<td>9-①</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Japanese Code</td>
<td>Classification</td>
<td>Approval Status</td>
</tr>
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<tr>
<td>Water jet knife unit</td>
<td>A surgical device utilizing high-pressure water jetting technology to incise the body tissues. It can make an extremely delicate and precise incision such as a low-pressure incision of the soft tissue without giving damage to the hard, elastic structure. It makes the surgical site clearly visible and allows the structure to be cleaned with water. It is used in various situations including treatment of skin burns or malignant tumors, resection of tumors or varicose veins. It may be used with a standard endoscope.</td>
<td>36961000</td>
<td>III 9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Water jet knife handpiece</td>
<td>A dedicated surgical device used as the cutting handpiece of a water jet cutting device. The surgeon holds it in his/her hand and uses it as a severing device.</td>
<td>37570000</td>
<td>III 9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgical robot unit</td>
<td>An operation support device that performs treatment of tissues including suturing, detaching and severing, and installing a prosthesis. It is used in open surgery or endoscopic surgery. The control system is based on computer technology. It usually consists of a series of systems including an operator console, arms for device operation. It may be used as a supporting device for training of surgeons.</td>
<td>38678000</td>
<td>III 9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgical robot navigation unit</td>
<td>A unit used for navigation (e.g., for placement of pedicle screws in spinal surgery) during surgery. This unit is based on computer technology and consists of an operator console, an image processing analyzer, etc. A position-detecting device, which is used to follow the surgical devices, is connected to the unit. Usually, information to be entered into the computer includes that related to CT or MRI, ultrasound, fluoroscopy, and anatomical landmarks. However, in some cases, preoperative images may not be used. The unit uses space coordinates obtained from the information mentioned above as a template, and follows the movement of the surgical device also by means of reading the location point in order to obtain precise 3D images showing the device and its angle. It is also used as a device to assist in the training of surgeons.</td>
<td>38723013</td>
<td>III 9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Neurosurgical navigation unit</td>
<td>A device that provides spatial positioning information about apparatus used during neurosurgery, neurosurgery/orthopedic surgery, and other types of surgery. This device is based on computer technology, and usually consists of a surgeon's console and an apparatus positioning detector. Usually, preoperative CT and MRI scans are used to input an image into a computer, and information from the positioning detector is overlaid on the image in the surgeon's console to keep track of correct spatial positioning information regarding the probe and other apparatus.</td>
<td>38723023</td>
<td>III 6,7-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug-containing dental tooth surface cleaner auxiliary material</td>
<td>An auxiliary cleaning material containing pharmaceutical agents. It is applied to the stained tooth after mechanical cleaning of the tooth surface.</td>
<td>70709000</td>
<td>III 5-②,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental multi-purpose ultrasonic therapy/general-purpose electrosurgery combined unit</td>
<td>An integrated system combining an ultrasonic instrument and an electrosurgical unit. It is used in dental treatment.</td>
<td>70721000</td>
<td>III 9-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug-containing dental zinc phosphate cement</td>
<td>A material made from the reaction of oxide powder (the main material: zinc oxide) with a phosphoric acid aqueous solution (it may contain metal ions). It contains pharmaceutical ingredients. It is used as a cementing agent that bonds a dental restoration to the hard tissue of oral cavity or other devices, a lining of a restoration and a temporary restorative material.</td>
<td>16710003</td>
<td>III 8-①,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug-containing dental polycarboxylate cement</td>
<td>A cement made from the reaction of zinc oxide with an aqueous solution of polyacrylic acid or of a similar polycarboxylic acid compound, or from the reaction of zinc oxide and polycarboxylic acid powder with water. It contains pharmaceutical ingredients. It is used as a cementing agent that bonds a dental restoration to the hard tissue of oral cavity or other devices, a lining of a restoration and a temporary restorative material.</td>
<td>16705003</td>
<td>III 8-①,13</td>
<td>applicable</td>
</tr>
<tr>
<td>Drug-containing dental adhesive resin-modified cement</td>
<td>A material mainly made of resin or a resin containing inorganic powder. It contains pharmaceutical ingredients. It is used to bond a dental prosthesis, etc. It may contain a dental dentin adhesive, a dental etching material, etc.</td>
<td>70836003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental composite resin-modified cement</td>
<td>A cementing material for a dental prosthesis, etc. It is mainly made of resin or a resin-containing inorganic powder. It contains pharmaceutical ingredients. It does not adhere to the tooth substance.</td>
<td>70837003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental zinc oxide eugenol cement</td>
<td>A hydrophobic material containing eugenol that reacts with zinc oxide, an accelerant, rubber, resin and an inactive inorganic filler. It contains pharmaceutical ingredients. It is used as a temporary restorative material, a lining (of a restorative material) and a material for relining a cavity in operative dentistry.</td>
<td>16709003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental zinc oxide non-eugenol cement</td>
<td>A cementing material for a dental prosthesis. It is mainly made of zinc oxide and fatty acids and contains pharmaceutical ingredients. It is called non-eugenol since it does not contain eugenol.</td>
<td>70838003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental glass polyalkenoate luting cement</td>
<td>A cementing material for a dental prosthesis. It contains pharmaceutical ingredients. It derives from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution.</td>
<td>70839003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing resin-modified dental glass-polyalkenoate/resin combined luting cement</td>
<td>A luting and bonding material for a dental restoration, dental prosthesis, orthodontic appliance, etc. It is resin-modified glass polyalkenoate cement component for dental luting applications. It contains pharmaceutical ingredients.</td>
<td>70841003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental filling composite resin for indirect restoration</td>
<td>A material for mixing or polymerizing (with external energy). It is made mainly of resin and an inorganic or composite filler. It contains pharmaceutical ingredients. It is used mainly in filling and restoration of the dental cavity or in repair of an artificial crown.</td>
<td>70847003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing polymer-based bracket adhesive and tooth conditioner</td>
<td>A bracket adhesive resin and a tooth surface conditioning material are the bonding materials made of polymethyl methacrylate, etc. They are used to bond an orthodontic bracket to the tooth surface. It contains pharmaceutical ingredients.</td>
<td>31750003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental dentin adhesive</td>
<td>A material mainly used to accelerate dentin bonding of composite resins, restorations or cementing agents. It contains pharmaceutical ingredients. It can be used as an enamel bonding agent.</td>
<td>42483003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental filling glass polyalkeonate cement</td>
<td>A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for filling and restoration of the tooth.</td>
<td>70848003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental core build-up glass polyalkenoate cement</td>
<td>A cement made from the reaction of aluminosilicate glass powder or powder of melted glass and metal with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients and may contain metal powder. It is used for core build-up.</td>
<td>70849013</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental core build-up resin-modified glass-polyalkenoate cement</td>
<td>A material for core build-up. It is a combination of a resin component and a glass polyalkenoate cement component. It contains drug.</td>
<td>70849023</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental lining/basing glass polyalkenoate cement</td>
<td>A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for lining or relining.</td>
<td>70850003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental polymer-based pit/fissure sealing material</td>
<td>A resin material suitable for sealing dental pits and fissures. It contains pharmaceutical ingredients. This material cures by chemical polymerization or polymerization by external energy.</td>
<td>31780003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental pit/fissure sealing resin-modified glass polyalkenoate-based cement</td>
<td>A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for sealing pits and fissures.</td>
<td>70851013</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental pit/fissure sealing resin-modified glass polyalkenoate cement</td>
<td>A sealing material for pits and fissures. It is a combination of a resin component and glass polyalkenoate cement for dental sealing of pits and fissures. It contains pharmaceutical ingredients.</td>
<td>70851023</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Calcium hydroxide-based cavity-lining dental material</td>
<td>A material containing calcium hydroxide. It is used mainly for pulp capping.</td>
<td>16182000</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental pulp-capping material</td>
<td>A material used for pulp capping of a deep cavity. It contains pharmaceutical ingredients. It contains zinc oxide eugenol cement for pulp capping.</td>
<td>70852000</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental filling material kit</td>
<td>A kit for dental restorations. It consists of dental composite resins for restoration, etching materials, adhesives, etc. It contains pharmaceutical ingredients.</td>
<td>70853003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental filling resin-modified glass-polyalkenoate cement</td>
<td>A dental filling material. It is a combination of a resin component and a polyalkenoate cement component for dental filling. It contains pharmaceutical ingredients.</td>
<td>70854003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental composite resins for indirect restoration</td>
<td>A material for polymerizing with external energy. It is made mainly of resin and an inorganic or composite filler. It contains pharmaceutical ingredients. It is used to fabricate a crown or inlay on the tooth in cavity preparation or on its model, and to create a dental restoration by polymerization.</td>
<td>70855003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing tooth surface coating material</td>
<td>A low viscosity resin material used for tooth surface coating. It contains pharmaceutical ingredients. A kit of this material and other materials is included.</td>
<td>70861003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing tooth surface conditioning material</td>
<td>A material used to treat the tooth surface after cavity preparation or root canal preparation. It contains pharmaceutical ingredients.</td>
<td>70862000</td>
<td>III</td>
<td>6,13</td>
</tr>
<tr>
<td>Drug-containing dental polymer-based cavity lining/basing material</td>
<td>A polymer-based lining material such as glass polyalkenoate cement. It contains drug.</td>
<td>70863003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Kit for drug-containing dental composite resins for indirect restoration</td>
<td>A kit consisting of a dental composite resin for indirect dental restoration, dental cement and an etching material which are used concurrently. It has components containing pharmaceutical ingredients.</td>
<td>70864003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental core build-up material kit</td>
<td>A kit for dental restoration consisting of materials for dental core build-up, dental etching material, dental dentin adhesive, etc. It has components containing pharmaceutical ingredients.</td>
<td>70865003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Drug-containing dental dentin adhesive kit</td>
<td>A kit consisting of materials for dental dentin adhesive and dental etching material. It may contain other pertinent devices. It has components containing pharmaceutical ingredients.</td>
<td>70866003</td>
<td>III</td>
<td>8-①,13</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Reg</td>
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<tr>
<td>Drug-containing dental polymer-based temporary sealing material</td>
<td>Drug-containing dental temporary sealing material</td>
<td>70870003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental temporary sealing material</td>
<td>Drug-containing dental temporary sealing material</td>
<td>70870003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental periodontal dressing</td>
<td>Drug-containing dental periodontal dressing</td>
<td>70872000</td>
<td>III</td>
<td>7&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental root canal sealing material</td>
<td>Drug-containing dental root canal sealing material</td>
<td>70871003</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Calcium hydroxide-based dental root canal filling material</td>
<td>Calcium hydroxide-based dental root canal filling material</td>
<td>70876000</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Iodoform root canal filling material</td>
<td>Iodoform root canal filling material</td>
<td>70877000</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing dental multipurpose glass polyalkenoate cement</td>
<td>Drug-containing dental multipurpose glass polyalkenoate cement</td>
<td>70880000</td>
<td>III</td>
<td>8&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing gingival retraction cord</td>
<td>Drug-containing gingival retraction cord</td>
<td>35861003</td>
<td>III</td>
<td>5&lt;①,13</td>
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<td>Drug-containing gingival retraction material</td>
<td>Drug-containing gingival retraction material</td>
<td>70880000</td>
<td>III</td>
<td>5&lt;①,13</td>
</tr>
<tr>
<td>Drug-containing tooth polishing abrasive</td>
<td>Drug-containing tooth polishing abrasive</td>
<td>70905000</td>
<td>III</td>
<td>7&lt;①</td>
</tr>
<tr>
<td>Dental bone reconstruction implant materials</td>
<td>Dental bone reconstruction implant materials</td>
<td>34006009</td>
<td>III</td>
<td>8</td>
</tr>
<tr>
<td>Non-absorbable dental bone reconstruction implant materials</td>
<td>Non-absorbable dental bone reconstruction implant materials</td>
<td>34006003</td>
<td>III</td>
<td>8</td>
</tr>
<tr>
<td>Dental endosseous implant</td>
<td>Dental endosseous implant</td>
<td>42347000</td>
<td>III</td>
<td>8</td>
</tr>
<tr>
<td>Dental implant fixture</td>
<td>Dental implant fixture</td>
<td>42348000</td>
<td>III</td>
<td>8</td>
</tr>
<tr>
<td>Dental submucosal implant</td>
<td>Dental submucosal implant</td>
<td>42349000</td>
<td>III</td>
<td>8</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Category</td>
<td>Risk Code</td>
<td>Applicability</td>
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</tr>
<tr>
<td>42350000</td>
<td>Dental intramucosal implant A dental implant to be implanted in the soft tissue in the oral cavity.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>42352000</td>
<td>Dental subperiosteal implant A dental implant to be implanted between the periosteum and the bone surface.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>42353000</td>
<td>Dental transendodontic and transradicular implant A rod-shaped implant to be inserted into the bone through the root canal or the root.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>42354000</td>
<td>Dental transgingival implant A dental implant used to prevent detachment of a dental prosthesis. It has an abutment structure extending into the oral cavity via the mucosa.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>70909000</td>
<td>Dental implant system A system consisting of dental implants, dental implant abutments, surgical instruments for implants, and dental laboratory tools used for fabrication of the superstructure of an implant.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>70910000</td>
<td>Dental implant abutment A device to be fixed to a dental implant fixture to serve as a support for the superstructure, or to be used temporarily until the gingiva is healed.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>38783000</td>
<td>Dental caries removal solution A liquid used to detect and remove dental caries in the tissue of the affected tooth.</td>
<td>III</td>
<td>6,13</td>
<td>applicable</td>
</tr>
<tr>
<td>38785000</td>
<td>Dental bleaching agent A dental liquid or paste used to whiten the teeth for treatment or cosmetic purposes.</td>
<td>III</td>
<td>6,13</td>
<td>applicable</td>
</tr>
<tr>
<td>70913000</td>
<td>Drug-containing dental hypersensitive dentine desensitizer A material applied to the tooth surface in order to control hyperesthesia of the dentin (including the molded surface). It contains pharmaceutical ingredients.</td>
<td>III</td>
<td>8&lt;1,13</td>
<td>applicable</td>
</tr>
<tr>
<td>70920003</td>
<td>Drug-containing dental adhesive material kit A kit consisting of devices used for standard dental adhesion. It contains pharmaceutical ingredients. Devices with other specified names are excluded.</td>
<td>III</td>
<td>8&lt;1,13</td>
<td>applicable</td>
</tr>
<tr>
<td>70928003</td>
<td>Drug-containing endodontic instrumentation aid dental material A material used to demineralize and soften the dental hard tissues in the cavity and the root canal wall. It contains pharmaceutical ingredients. It is also used to assist root canal enlargement with a reamer or a file, to float cutting debris with foams and to clean the root canal wall. There is a kit that contains the devices used to apply the materials.</td>
<td>III</td>
<td>5&lt;1,13</td>
<td>applicable</td>
</tr>
<tr>
<td>42848000</td>
<td>Orthopaedic spine external fixation system An orthopedic system designed for a specific surgical procedure. It is used to correct vertebral misalignment and fix vertebrae in their proper position and adjust extracorporeally to promote cure. Usually, it contains a case tray, external components and a large number of implants (e.g., Steinmann pins, Schanz screws, Kirschner wires) as well as appropriate measuring devices. Implants are replenished when used in order to maintain this system. The external fixation device contained in this system is reusable in accordance with instructions provided by the manufacturer.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
</tr>
<tr>
<td>32803000</td>
<td>Reusable colored vision corrective contact lens A vision-correcting ophthalmic lens containing colorants and/or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is reusable.</td>
<td>III</td>
<td>5&lt;3</td>
<td>applicable</td>
</tr>
<tr>
<td>36055000</td>
<td>Reusable vision corrective contact lens A vision-correcting ophthalmic lens which does not contain either colorants or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is reusable.</td>
<td>III</td>
<td>5&lt;3</td>
<td>applicable</td>
</tr>
<tr>
<td>37581000</td>
<td>Single-use vision corrective contact lens A vision-correcting ophthalmic lens which does not contain either colorants or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.</td>
<td>III</td>
<td>5&lt;3</td>
<td>applicable</td>
</tr>
</tbody>
</table>
| Description                                                                 | Description                                                                                                                                                                                                 | Number     | Category | Code    | Applicability | N/A
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Single-use colored vision corrective contact lens</td>
<td>A vision-correcting ophthalmic lens containing colorants and/or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.</td>
<td>37583000</td>
<td>III</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Therapeutic contact lens</td>
<td>A device designed to be worn over the front surface of the eye. It is used to protect the eye, to seal the anterior chamber, to deliver drugs, to change the corneal curvature, or to treat the retina in a special way.</td>
<td>36054000</td>
<td>III</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Collagen-containing eye protector</td>
<td>A mechanical eye shield (a corneal shield) placed over the eye surface to protect the cornea. It is made of collagen. For instance, it may allow clinical observation during regeneration of the corneal epithelium, and the patient's field of vision can be partially restored.</td>
<td>17652000</td>
<td>III</td>
<td>5-③,14</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Intra-uterine contraceptive device</td>
<td>A device used to avoid pregnancy during sexual intercourse. It is placed in the upper uterine fundus and a thread extending from the device is inserted into the vagina through the orifice of the uterus.</td>
<td>35125000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Contraceptive fallopian tube insert</td>
<td>An implantable device applied to the fallopian tube in tubal ligation to prevent an ovum from passing through. This device is a plug or valve inserted into the fallopian tube and considered to be a kind of contraceptive device.</td>
<td>32678000</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable bone-conduction hearing aid</td>
<td>A hearing aid that uses bone conduction output via a transducer. Its vibrating part is installed directly on the cranial.</td>
<td>34180000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Endoscopy submucosal injection material</td>
<td>A solution, etc., that is injected into the submucosa in the lesion site in endoscopic mucosal resection. It separates and lifts the mucosal layer and muscular layer, and maintains this state to improve the operability of resection and detachment in the lesion site.</td>
<td>71028000</td>
<td>III</td>
<td>6-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Carotid artery stent</td>
<td>A stent with a support structure expanded and placed in a carotid artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in the place as a permanent implant. It is made of metals, polymers, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>45851000</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central circulatory catheter for trapping embolus</td>
<td>A catheter system for blood vessels of the central circulatory system for capture and remove emboli (blood clots and fragments) during blood vessel plasty and stent placement. It is equipped with an embolus capturing filter or an occlusion balloon at the tip. This device is for single-use.</td>
<td>44841004</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Extracorporeal shockwave pain treatment device</td>
<td>A device that delivers a shock wave from outside the body to eliminate pain and for palliative treatment. An extracorporeal lithotripter is excluded.</td>
<td>71029000</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Implantable electrocardiographic data recorder</td>
<td>A device implanted under skin to measure and record cardiac activity and biological functional phenomena. It contains a battery and a circuit that senses cardiac activity and biological functional phenomena. The data are stored in the device. Generally, a non-invasive programmer is used for programming and displaying stored data.</td>
<td>71030000</td>
<td>IV</td>
<td>8-④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable orthokeratology contact lens</td>
<td>A gas-permeable hard contact lens for orthokeratology. It is directly worn on the front surface of the eye, and changes the corneal shape to correct the uncorrected vision after the lens is removed. Usually, it is used under medical supervision. This device is reusable.</td>
<td>47926000</td>
<td>III</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Radiation therapy synchronizer</strong></td>
<td>A physiological monitoring device used as one of the components of radiotherapy equipment. It produces signals that enable synchronization of radiotherapy with measurable physiological parameters (such as respiration information or heart rate information of a patient). It is used for respiratory-gated treatment. A device used for respiratory-gated imaging as one of the components of a diagnostic imaging system is included.</td>
<td>47928000</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
<td>applicable</td>
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<tr>
<td><strong>Catheter for penetrating vascular stenosis</strong></td>
<td>A catheter used to secure a passage for a guide wire in percutaneous blood vessel plasty for patients where passage of the guide wire is difficult due to stenosis in arteries, veins or shunts except for the coronary artery and intracranial cerebral blood vessels.</td>
<td>46916000</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Glucose monitor system</strong></td>
<td>A system that continuously measures the glucose level in the blood or body fluid. Usually it consists of an electrochemical sensor inserted subcutaneously and a portable receiver, which receives an electrical signal derive from the sensor electrodes, converts it to the glucose level, and stores and displays the level.</td>
<td>44611003</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Negative pressure wound therapy system</strong></td>
<td>A system that adds controlled negative pressure, helps protect wounds, promotes granuloma formation, and removes exudates and infectious wastes to promote wound healing. Usually, it consists of a monitoring unit for negative pressure maintenance, a foam dressing, a film drape, a connecting tube and an exudate reservoir.</td>
<td>20395000</td>
<td>III</td>
<td>4-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable decorative contact lens</strong></td>
<td>An ophthalmic lens that is not vision-correcting, to be worn directly on the surface of the eye. Lenses for vision correction purposes are not included. Lenses are included that are intended to change the appearance of the iris or pupil (color, pattern, or shape) when they are worn. Normally, lenses should be used under the instruction of a physician. The device is reusable.</td>
<td>47837000</td>
<td>III</td>
<td>5-③&quot;</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use decorative contact lens</strong></td>
<td>An ophthalmic lens that is not vision-correcting, to be worn directly on the surface of the eye. Lenses for sight correction purposes are not included. Lenses are included that are intended to change the appearance of the iris or pupil (color, pattern, or shape) when they are worn. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.</td>
<td>47836000</td>
<td>III</td>
<td>5-③&quot;</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Vesicoureteral reflux treatment injectable material</strong></td>
<td>An injection material containing dextranomer beads, etc. as a main component, a swelling formation material. It is cystoscopically and transurethrally inserted into the submucosa near the ureteral orifice or of the intramural ureter in the bladder for treatment of vesicoureteral reflux.</td>
<td>17876013</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Posterior chamber lens with crystalline lens</strong></td>
<td>A device that is permanently implanted into the posterior chamber of the eye for vision correction in a patient with refractive error. It is inserted into the posterior chamber of the phakic eye. Generally, it is a lens made of plastic/synthetic resin.</td>
<td>47413000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Vibrating peripheral vessel penetration catheter system</strong></td>
<td>A system that generates or transmits oscillation in the catheter tip in order to penetrate completely occluded sites in peripheral vessels.</td>
<td>46850004</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Antimicrobial catheter cover material</strong></td>
<td>A sterilized cover/protective material such as adhesive film materials impregnated with a disinfectant and an antibacterial agent. Directly applied to the injection needle or catheter puncture site to fix them. Non woven cloth may be added in order to strengthen the fixation and retention.</td>
<td>47937003</td>
<td>III</td>
<td>13</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Reference</td>
<td>Class</td>
<td>Applicability</td>
<td>Remarks</td>
<td></td>
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<tr>
<td>Antimicrobial ventilation tracheal tube</td>
<td>A cylindrical tube to be inserted into the trachea from the oral cavity or nasal cavity for securing the airway, administration of inhalational anesthetics or medical gases and ventilation. It is coated with substances having antibacterial properties for prevention of infection. It may be packaged with a connector that connects to the breathing circuit or a manual resuscitator.</td>
<td>46877003</td>
<td>III</td>
<td>13</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use interspinous placement</td>
<td>A device to be placed between the spinous processes to relieve lower limb pain and leg pain. With the placement, it holds the lumbar spine in the flexed position and prevents it from being in the extended position whenever possible.</td>
<td>47023003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bovine pericardial patch</td>
<td>A device used for closure and repair of septal defects, damaged cardiac muscle, tissue, pericardium or a blood vessel opening produced during surgery. It is made of bovine pericardium.</td>
<td>35273404</td>
<td>IV</td>
<td>8-②, 14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood component separation kit</td>
<td>A kit consisting of a blood component processor, collecting bags, a sprayer, etc. The blood component processor is used with a system such as an apheresis system for separating, collecting and administering specific blood components. The kit is for single-use.</td>
<td>58331003</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Shunt for fetal pleural effusion</td>
<td>A shunt tube and delivery system used to continuously drain fetal pleural effusion to the maternal amniotic cavity.</td>
<td>71031000</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-absorbable local hemostatic material for central circulation system</td>
<td>A non-absorbable local hemostatic device used for surgical openings, skin wounds or internal structures to achieve hemostasis in blood vessels of the central circulatory system.</td>
<td>31744024</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable clamp for cranial fixation</td>
<td>An absorbable, implantable fixation device that is used for cranial closure after craniotomy, or to pinch cranial fragments together for fixation in order to restore dislocation after complicated fracture of skull. Plates, discs, and auxiliary pins are used for fixation.</td>
<td>70500004</td>
<td>IV</td>
<td>8-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Drug-eluting stent for femoral artery</td>
<td>A drug-eluting stent with a support structure expanded and placed in a femoral artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in the place as a permanent implant. It is made of metals, polymers, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>46919004</td>
<td>IV</td>
<td>13</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Percutaneous central venous temperature control device</td>
<td>A control system that adjust body temperature by heat exchange with the blood via a reflux catheter placed in the central veins of patients who need body temperature control. It consists of a catheter through which reflux liquid circulates, and a control unit for temperature control, circulation, a body temperature monitor, and an alarm etc.</td>
<td>44710004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Balloon catheter for neuroendoscopy</td>
<td>A balloon catheter used with a dedicated endoscope for endoscopic nerve treatment. The catheter is inserted into the cerebral ventricles etc. via an endoscope channel. It operates without electricity (e.g., radio-frequency waves, electromagnetic energy, ultrasound and laser energy). This device is for single-use.</td>
<td>71032000</td>
<td>IV</td>
<td>6-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood coagulation analyzer for self monitoring</td>
<td>An automatic or semi-automatic device dedicated for self monitoring including qualitative and quantitative analyses of hemostatic components (suppression of bleeding) such as fibrinogen, fibrin and platelet, and the time to hemostasis.</td>
<td>56687003</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Orthodontic anchor screw</strong></td>
<td>A small, metal screw used as an anchorage unit to provide the orthodontic force in orthodontic therapy. The screw is planted and fixed in the oral cavity jawbone, and an orthodontic tool is connected to the head of the screw. It is used as the anchorage unit to provide the orthodontic force for movement of the teeth. A self-tapping type and a self-drilling type are available. The screw is removed after orthodontic therapy. This device is for single-use.</td>
<td>46536003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Vascular graft with bovine-derived valve</strong></td>
<td>A device that combines a bovine-derived valve with a bovine cervical vein or artificial blood vessel used for pulmonary artery replacement (including re-replacement). Usually, used for treatment of congenital heart abnormalities.</td>
<td>46422014</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Catheter for replacement of coronary catheter</strong></td>
<td>A flexible tube with a balloon at the distal end. The device is used to fix the guide wire in the guiding catheter by controlling the dilation of the balloon when replacing the catheters.</td>
<td>17846124</td>
<td>IV</td>
<td>6-⑤</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Arteriovenous cannula for central circulatory system</strong></td>
<td>A semi-rigid or rigid tube to be inserted into a blood vessel other than in a thoracotomy site, and used as a guide path for fluid in the blood vessel in areas including the central circulatory system. This device is for single-use.</td>
<td>47733104</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Single-use negative pressure wound therapy system</strong></td>
<td>A system that adds controlled negative pressure, helps to protect wounds, promotes granuloma formation, and removes exudate and infectious wastes to promote wound healing. Usually, it consists of a monitoring unit for negative pressure maintenance, a foam dressing, a film drape, a connecting tube and an exudate reservoir. It is for single-use.</td>
<td>58202003</td>
<td>III</td>
<td>4-①</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Filling material for tracheobronchial</strong></td>
<td>An occlusion plug made of resin that is filled to the bronchus. It is used to maintain occlusion for the purpose of stopping air leakage or closure of a fistula. Held with straight grasping forceps bronchoscopically, the usually filler is usually placed in the bronchus where air leakage or a fistula is confirmed.</td>
<td>35458113</td>
<td>III</td>
<td>5-④</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Collagen-containing absorbable nerve regeneration inducing material</strong></td>
<td>An absorbable, collagen-containing device that is inserted in the site of laceration or defect of peripheral nerve due to trauma or other causes in order to induce nerve regeneration and restore function by giving continuity to the both nerve stumps.</td>
<td>71034004</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Transcatheter bovine cardiac valve</strong></td>
<td>An artificial heart valve (bovine pericardial valve) placed using a catheter. Usually, it is used for treatment of acquired or congenital valvular diseases, and mainly made of bovine pericardium. Some valves include a delivery system.</td>
<td>60245004</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Wearable automatic defibrillator</strong></td>
<td>A wearable device that continuously monitors the ECG with electrodes placed on the body surface for restoration of normal heart rate. When tachycardia is detected, it automatically delivers defibrillation pulses from the defibrillation electrodes on the body surface to the cardiac muscle.</td>
<td>48051003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Heparin-coated central circulatory arteriovenous cannula</strong></td>
<td>A semi-rigid or rigid heparin-coated tube to be inserted into a blood vessel other than in a thoracotomy site, and used as a guide path for fluid in the blood vessel in areas including the central circulatory system. This device is for single-use.</td>
<td>47733204</td>
<td>IV</td>
<td>7-⑥,14</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Local hemostasis material using gelatin containing human thrombin</strong></td>
<td>A gelatin-based device with human thrombin applied to the surgical incision openings, the skin wound and the internal structure for local hemostasis that is made of a material absorbed in the body, optionally with adhesive effect.</td>
<td>35895324</td>
<td>IV</td>
<td>8-⑤,14</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Equine cardiac valve</strong></td>
<td>An artificial heart valve (equine pericardial valve) used for heart valve replacement. Usually, it is used for treatment of acquired or congenital valvular diseases, and is mainly made of equine pericardium.</td>
<td>35591404</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Patient-adaptive implantable fixation plate</strong></td>
<td>A non-absorbable, implantable fixation device that fills the space between the fractured bones in the treatment of bone deformity or fracture. It is attached to the fractured bone with screws, etc. to protect the fracture site from stress. It is custom designed and manufactured to fit an individual patient. It may be used in distraction osteogenesis of pathological fractures and for reinforcement in cranial and maxillofacial surgical procedures and articular fusion requiring fusion surgery. Usually, the bone plate is made of metal, carbon, etc.</td>
<td>35241023</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Catheter system for bronchial thermoplasty</strong></td>
<td>A catheter system that delivers a high-frequency current via a catheter that is placed in contact with the bronchial area. It consists of a catheter, a main unit that generates a high-frequency current and the related accessories.</td>
<td>44775003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Thulium/YAG laser</strong></td>
<td>A laser used in surgical procedures, etc. It utilizes a crystal consisting of thulium (Tm) and yttrium, aluminum and garnet (YAG) as the substrate.</td>
<td>71037003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Transcatheter porcine pericardial valve</strong></td>
<td>An artificial heart valve (porcine pericardial valve) placed using a catheter. Usually, it is used for treatment of acquired or congenital valvular diseases, and consists mainly of porcine pericardium. Some include a delivery system.</td>
<td>60245114</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Malignant tumors treatment using alternating electric field</strong></td>
<td>A portable device that exposes a specific body site to an alternating electric field by means of externally placed electrodes. It treats malignant tumors, etc. by inhibiting cell division.</td>
<td>58845003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Single-use probe for PDT semiconductor laser</strong></td>
<td>A device dedicated for use with a PDT semi-conductor laser. This device is for single-use. It is connected to the PDT semi-conductor laser system and used to apply a laser having a specific wavelength to the tumor tissue where photosensitizers accumulate.</td>
<td>61471003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Control unit for central venous placement temperature management system</strong></td>
<td>A control unit that controls temperature and circulation of the perfusate circulating in the circulatory catheter of a temperature management system with percutaneously placed central venous catheters. It also monitors the body temperature and gives a warning, etc.</td>
<td>44709003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Software for high risk pharmacokinetic analyzer</strong></td>
<td>A software that performs pharmacokinetic analysis based on measurements of the blood concentrations of drugs which should be administered with caution, and supports determination of the dose and regimen of the drugs. This term may include recording media where the software are stored.</td>
<td>61215003</td>
<td>III</td>
<td>11,11-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Software for peritoneal dialysis treatment</strong></td>
<td>A software that performs prescription simulation of peritoneal dialysis based on the results obtained from a peritoneal function test (PFT), a peritoneal equilibration test (PET) and a body composition analyzer. It supports preparation of a dialysis treatment plan. The dialysis conditions that are determined based on the simulation are set in an automated peritoneal dialysis system. This term may involve the recording media where the software are stored.</td>
<td>41049003</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Software for radiation planning</strong></td>
<td>A software that calculates and displays the area to be treated with radiation and the internal dose distribution based on the results obtained with CT systems etc., and supports the radiotherapy planning. This term may involve the recording media where the software are stored. The dose distribution may be not calculated.</td>
<td>40887003</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Software for radiotherapy QAQC planning</strong></td>
<td>A software that verifies the validity of the radiotherapy plan by recalculation of the dose and the MU value calculated with the radiotherapy planning system software and radiotherapy planning system. This term may involve the recording media where the software are stored.</td>
<td>40887013</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Device Description</td>
<td>Classification</td>
<td>Approval Numbers</td>
<td>Applicable</td>
<td>Notes</td>
<td></td>
<td></td>
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<td>----------------------------------------------------------------------------------</td>
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<tr>
<td>Software for ophthalmic surgery treatment planning</td>
<td></td>
<td>71039003</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A software for intended to aid ophthalmic surgical planning based on measurement of the eye prior to the surgery. It simulates surgical results. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Implantable clip for heart</td>
<td></td>
<td>35649004</td>
<td>IV</td>
<td>⑧-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>An implantable metal device. It is indicated for use in the heart, and is used to prevent blood flow in such anatomical sites as the left atrial appendage.</td>
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</tr>
<tr>
<td>Heparin-coated stent-graft for blood vessels</td>
<td></td>
<td>47932003</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A heparin-coated device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the peripheral blood vessel in order to maintain the patency of the vessel. The stent-graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent-graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.</td>
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</tr>
<tr>
<td>Heparin-coated stent-graft for central circulatory system</td>
<td></td>
<td>47932014</td>
<td>IV</td>
<td>8-②,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A heparin-coated device with artificial material inside, outside, or both sides of support structure (stent) or between stents, that remains inside a blood vessel. This device is inserted into the blood vessel of the central circulatory system in order to maintain the patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. Some are tubular or branched.</td>
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</tr>
<tr>
<td>Reusable limbal supported Contact lens for abnormal cornea shape</td>
<td></td>
<td>71050003</td>
<td>III</td>
<td>5-③'</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A contact lens that can correct vision in the eye having an irregularly shaped cornea. The lens is directly worn on the front surface of the eye. The lens has a special shape that allows it to be retained between the corneal limbus and conjunctiva, and to make the artificial tear exchangeable. Usually, it is used under medical supervision. This device is reusable.</td>
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</tr>
<tr>
<td>Software for parameter selection of electrical stimulator</td>
<td></td>
<td>71051003</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A software used to transmit electrical operating characteristics noninvasively to the base therapeutic system and change the characteristics. The software does not control the entire therapeutic system. It can change a certain range of the characteristics which are selected by a physician or under a physician's direction within a pre-specified range in the implantable or extracorporeal base electrical stimulator. It may provide patient information stored in the electric stimulator. This term may involve the recording media where the software are stored.</td>
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</tr>
<tr>
<td>Cardiac electrosurgical unit</td>
<td></td>
<td>60784004</td>
<td>IV</td>
<td>6-⑤,9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A unit used to cauterize/coagulate cardiac muscle tissue by direct contact using high frequency radio waves. It consists of a generator, and a probe etc.</td>
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<tr>
<td>Cardiac cryosurgical unit</td>
<td></td>
<td>60721004</td>
<td>IV</td>
<td>6-⑤,9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A unit used for cryocoagulation of the cardiac tissue by direct contact with a chilled probe. It consists of a generator and a probe etc.</td>
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</tr>
<tr>
<td>Heparin-coated drain for intraocular</td>
<td></td>
<td>61127003</td>
<td>III</td>
<td>8,14</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>A heparin-coated artificial drain that is implanted intraocularly to mitigate increased intraocular pressure.</td>
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</tr>
<tr>
<td>Implantable accessory for implanted cardiac pacemaker</td>
<td></td>
<td>44900003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>An accessories used in the implantation procedure of an implantable cardioverter-defibrillator and pacemaker system. The accessories consist of a sleeve used for lead fixation, a plug used to occlude the unused connector port, a cap used to insulate an unused lead connector, and other non-active devices implanted with the implantable cardioverter-defibrillator and pacemaker system.</td>
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</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable Terms</td>
<td>Applicable Notes</td>
<td></td>
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<tr>
<td>----------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Controller for temporary non-roller type cardiac support blood pump</strong></td>
<td>A drive unit that operates and monitors an implantable, intracardiac pump catheter for circulatory assistance. The pump catheter provides circulatory assistance in emergency care of patients with acute cardiac failure, such as cardiogenic shock, or in patients in whom normal cardiac function is impaired during cardiac catheterization or surgical treatment, by bypassing the aortic valve and expelling the blood. It may have various monitoring functions.</td>
<td>57808003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Catheter for temporary non-roller type cardiac support blood pump</strong></td>
<td>A pump catheter for emergency use that supports circulation by bypassing the aortic valve and delivering the blood in patients with acute cardiac failure such as cardiogenic shock, and patients whose normal cardiac function is lost in cardiac catheter treatment or surgical treatment. It is inserted in the heart percutaneously or via blood vessel to implant, and used with a dedicated driving device.</td>
<td>56732004</td>
<td>IV</td>
<td>7-①</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Software for active implanted device control</strong></td>
<td>A software used to transmit one or more electrical operating characteristics noninvasively to the active base unit and change the characteristics. The software does not control the entire therapeutic system. It can change a certain range of the characteristics which are selected by a physician or under a physician's direction within a pre-specified range in the implantable, programmable base unit. It may read out parameter values stored in active devices, transmit them to external devices and provide information about patient status. This term may involve the recording media where the software are stored.</td>
<td>71052003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Bioabsorbable coronary stent</strong></td>
<td>A stent with an absorbable support structure expanded and placed in a coronary vessel in order to maintain the patency of the coronary vessel. This device is delivered by a catheter to an occluded site. By the inflation of the balloon catheter, or self-expansion of the stent itself, this device expands and supports the blood vessel.</td>
<td>61535004</td>
<td>IV</td>
<td>8-②,8-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Catheter for replacement of pulmonary artery catheter</strong></td>
<td>A flexible tube with a balloon at the distal end. The device is used to fix the guide wire in the guiding catheter by controlling the dilation of balloon when replacing the catheter. The device is used for the pulmonary artery.</td>
<td>17846134</td>
<td>IV</td>
<td>6-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Focused ultrasound surgical system</strong></td>
<td>A system used to cauterize/coagulate the target tissue by heat of focused ultrasonic energy. The ultrasonic energy is supplied from transducer placed outside the patient's body or inserted into the local site. It may have a temperature monitor of target tissue or function of imaging monitor in addition to a control mechanism of transducer.</td>
<td>57888003</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Implantable leadless cardiac pacemaker</strong></td>
<td>An electrode-integrated pacemaker which is placed inside the heart percutaneously by catheter. It is sealed in a sealed case, with a built-in battery, electrical pulse generating circuit, and electrodes, etc., and is equipped with a circuit that senses cardiac activity. Some include a delivery system.</td>
<td>60789004</td>
<td>IV</td>
<td>8-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Suture site reinforcement material</strong></td>
<td>A non-absorbable synthetic material used to reinforce suture site. The one to use in combination with an automatic suture unit is excluded.</td>
<td>70435013</td>
<td>III</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Halothane anaesthesia vaporizer</strong></td>
<td>A device used to vaporize the anesthetic halothane (also called Fluothane) and administer the gas to the patient before surgery, at a controlled rate. The device is usually attached to an anesthesia system or respirator.</td>
<td>36891000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Methoxyflurane anaesthesia vaporizer</strong></td>
<td>A device that vaporizes an anesthetic methoxyflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.</td>
<td>36984000</td>
<td>III</td>
<td>11-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Absorbable tissue spacer for radiotherapy</strong></td>
<td>An absorbable material used to reduce radiation exposure of normal tissue during radiotherapy by implanting surgically or percutaneously between tissue, internal organs, etc., to make a space between the malignant tumor and normal tissue.</td>
<td>60424004</td>
<td>IV</td>
<td>8-⑤</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicable</td>
<td>Notes</td>
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<td></td>
</tr>
<tr>
<td>Magnetic stimulator for transcranial treatment</td>
<td>A magnetic stimulator for treatment used to continuously stimulate the local region of cerebral cortex transcranially.</td>
<td>61124003</td>
<td>III</td>
<td>9①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Control device for cardiac/central circulatory catheter</td>
<td>A device to hold the catheter for applying cardiac or central circulatory region and to control it by magnetic or mechanical power. It is used to be controlled remotely by the operator.</td>
<td>71056003</td>
<td>III</td>
<td>6,7,9①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thyroid cartilage fixation device</td>
<td>A device used for maintaining dilatation of dissected thyroid cartilage during plastic surgery of pharynx for patient with vocal cord dysfunction. Usually, it is made of metal.</td>
<td>71057003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Percutaneous repair system for mitral valve coaptation failure</td>
<td>An implantable device that is inserted percutaneously to repair the coaptation failure of mitral valve. Some include a delivery system.</td>
<td>56280004</td>
<td>IV</td>
<td>8②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Fistula formation prosthesis for pancreas</td>
<td>A prosthetic device used to pull the walls of gastrointestinal tract and neighboring pancreas cyst and form a fistula between them, through the gastrointestinal tract under endoscopic ultrasonographic guidance for therapeutic purpose. For example, indwelling part of the prosthesis is made of metal, and has double-walled flanges on the both side of edges that have gripping force to hold the two tissue walls.</td>
<td>62611003</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Software for analysis of germline gene variants (for eligibility identification of antineoplastic agents)</td>
<td>A software for medical device, which is used to identify eligibility for treatment with antineoplastic agents, based on information of variants derived from germline gene obtained from whole blood specimens. This term may include the recording media, etc. where the software are stored.</td>
<td>71058003</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>System for analysis of somatic cell gene variants (for eligibility identification of antineoplastic agents)</td>
<td>A system for analysis of gene variants used to conduct eligibility identification for treatment with antineoplastic agents, based on information of gene variants derived from somatic cell obtained from body tissue samples. This system consists of DNA sequencer, preparation reagents for sequencing sample, and software for analyzing, and may contain template preparation reagents as a component.</td>
<td>71059003</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable spacer for implantable device</td>
<td>An absorbable device used in combination with an apparatus placed in the body temporarily or permanently. This device is used to place the apparatuses in intended intervals, and may be used to intend for enhancing visibility, etc. Devices identified elsewhere are excluded.</td>
<td>71062004</td>
<td>IV</td>
<td>7④,8⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Information collating software for radiotherapy</td>
<td>A software that has function of collating the information such as irradiation parameter specified by a radiation planning software, and the condition that a radiotherapy equipment irradiates, on the occasion of the irradiation of X-ray in the radiotherapy. This term may involve the recording media where the software are stored.</td>
<td>40887023</td>
<td>III</td>
<td>9②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hypoglossal nerve electrical stimulator</td>
<td>An electrical nerve stimulator that induces contraction of muscles of tongue to improve airway patency by stimulating hypoglossal nerve. Usually, the stimulator consists of a pulse generator to be implanted in the anterior thoracic wall, an electrode to be implanted around hypoglossal nerve, and a lead connected to the pulse generator. Some include respiratory monitoring sensor and lead to be implanted in the intercostal muscles to stimulate in synchronization with the respiratory.</td>
<td>60360004</td>
<td>IV</td>
<td>8④</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Corneal curvature fluctuation meter</td>
<td>A device used to detect changes in corneal curvature, to be worn directly on the surface of the eye.</td>
<td>62111003</td>
<td>III</td>
<td>5②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Absorbable bone regeneration material containing human demineralized bone matrix</td>
<td>An absorbable material containing demineralized bone matrix derived from human allogeneic bone applied to lesions by covering, coating, or filling, to restore bone tissues.</td>
<td>47257004</td>
<td>IV</td>
<td>8②,14</td>
<td>applicable</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- Applicable: Indicates whether the device is applicable for the described medical condition.
- Classification: Indicates the classification level according to the regulatory framework (e.g., III, IV).
- N/A: Not available.
<table>
<thead>
<tr>
<th>Product Description</th>
<th>Description</th>
<th>Classification</th>
<th>Approval</th>
<th>Application</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adipose tissue separation kit</td>
<td>A dedicated kit used to separate and process adipose tissues for infusion of specific cells or tissues. This device may be used in combination with a cytology centrifuge, etc. This device is for single-use.</td>
<td>III</td>
<td>3</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Gene variants analysis set (for cancer genome profiling)</td>
<td>A gene variants analysis set used for cancer genome profiling based on information of gene variants obtained from body tissue samples. This set consists of software for analysis and preparation reagents for template DNA.</td>
<td>Ⅲ</td>
<td>—</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Implantable prostatic tissue retractor system</td>
<td>A system used for transurethral placement of an implant to retract the prostate tissue to maintain the patency of the urethra. This system consists of an implant made of suture threads and metal parts, an implant delivery device, etc.</td>
<td>Ⅲ</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Orthodontic anchorage device</td>
<td>A device consists of components of orthodontic appliance system such as a screw, a wire connected to the screw, and attachments which are used as an anchorage unit to provide an orthodontic force for movement of the teeth in orthodontic therapy. This device is removed after orthodontic treatment. This device is for single-use.</td>
<td>Ⅲ</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Open abdominal wound dressing kit</td>
<td>A dressing kit that covers an open abdominal wound with controlled negative pressure, helps protect the abdominal organs from outside the body, provides efficient drainage, suppresses inflammation, and reduces the edema to enable early peritoneal closure. Usually, it consists of a form dressing, drape, tubing set, and protection layers.</td>
<td>Ⅲ</td>
<td>4</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Software for gene variants analysis (for cancer genome profiling)</td>
<td>A software for gene variants analysis which is designed to perform cancer genome profiling based on information of gene variants obtained from body tissue samples. This term may involve recording media, etc. where the software are stored.</td>
<td>Ⅲ</td>
<td>—</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Supporting software for differential diagnosis with endoscopic imaging</td>
<td>A software, which is designed to process data obtained from an endoscopic image. The resultant data are provided for diagnostic, etc. It has functions to output numeric values and graphs based on quantitative data such as benign/malignant differentiation of lesion candidates, presenting candidates of diagnostic outcomes, and stage of disease progression. This term may involve recording media where the software are stored.</td>
<td>Ⅲ</td>
<td>10</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Software for analysis of somatic cell gene variants (for eligibility identification of antineoplastic agents)</td>
<td>A software, which is used to identify eligibility for treatment with antineoplastic agents based on the information of gene variants derived from somatic cell obtained from body tissue samples. This term may involve recording media where the software are stored.</td>
<td>Ⅲ</td>
<td>—</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Intracardiac prosthesis</td>
<td>An implantable artificial device to block the intracardiac blood flow to reduce thromboembolism. Clips or a devices used on pericardial defect lesions are excluded.</td>
<td>IV</td>
<td>8</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Collagen-containing absorbable artificial dura mater</td>
<td>A collagen-containing artificial membrane, which is made of materials to be absorbed in the body, used to supply or replace the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy.</td>
<td>IV</td>
<td>8, 8, 14</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Murine antibody-coated coronary stent</td>
<td>A stent with a support structure coated with a murine antibody expanded and placed in a coronary vessel in order to maintain the patency of the vessel. This device is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, this device expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant.</td>
<td>IV</td>
<td>8, 14</td>
<td>applicable</td>
<td>—</td>
</tr>
</tbody>
</table>
| Device Type | Description | Product Code | Class | Appendage Code | Applicability
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Gene variants analysis system (for cancer genome profiling)</td>
<td>A system for gene variants analysis which is designed to perform cancer genome profiling based on the information of gene variants obtained from body tissue samples. This system consists of DNA sequencer, preparation reagents for sequencing sample, and software for analyzing, and may contain template preparation reagents as a component.</td>
<td>60943033</td>
<td>III</td>
<td>—</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Gastronomy drug administration tube for long-term use</td>
<td>A hollow device to be placed surgically in the stomach, the duodenum or the jejunum for administration of drugs needing appropriate management about dosage, the rate of administration, etc. It is for long-term use.</td>
<td>71068004</td>
<td>IV</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Enteral drug administration pump</td>
<td>A portable pump used to administer drugs needing appropriate management about dosage, the rate of administration, etc., into the stomach, the duodenum or the jejunum.</td>
<td>13215013</td>
<td>III</td>
<td>11-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Vena cava stent</td>
<td>A stent with a support structure expanded and placed in the vena cava in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.</td>
<td>71070004</td>
<td>IV</td>
<td>8-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed cardiac catheter-tip electrode</td>
<td>A conductor installed at one end of a flexible tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing and defibrillation. This product is a reprocessed single-use device.</td>
<td>46359004</td>
<td>IV</td>
<td>7-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for analysis of germline gene variants (for identification of morbid risk)</td>
<td>A software for a medical device which is used to determine pathological variants and identify morbid risk based on information on variants derived from germline gene obtained from whole blood specimens. This term may include the recording media, etc. where the software is stored.</td>
<td>71058013</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
</tr>
<tr>
<td>Neutron irradiator for boron neutron capture therapy</td>
<td>A device that irradiates the affected area by producing high-energy protons and causing them to collide with a suitable target to emit the neutrons used in boron neutron capture therapy. It is mainly used in the treatment of cancer. It consists of an accelerator that accelerates protons to high energy and a neutron radiating device, etc. and may have a proton transport device. Generally, it is equipped with an ion source, a target, a moderator, a collimator, a positioning device, a movable table, an operator console, etc.</td>
<td>71077003</td>
<td>III</td>
<td>9-①</td>
<td>applicable applicable</td>
</tr>
<tr>
<td>Software for boron neutron capture therapy treatment planning</td>
<td>A software that calculates and displays the area to be treated and internal dose distribution, based on the results obtained from CT systems, etc., and supports the treatment planning when boron neutron capture therapy is performed. This term may involve the recording media where the software are stored.</td>
<td>71078003</td>
<td>III</td>
<td>9-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Somatic cell gene variants analysis set (for eligibility identification of antineoplastic agents)</td>
<td>A gene variants analysis set used to identify eligibility for treatment with antineoplastic agents, based on information on gene variants derived from somatic cell obtained from body tissue samples. It consists of software for analysis and preparation reagents for template DNA.</td>
<td>71059023</td>
<td>III</td>
<td>—</td>
<td>applicable</td>
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<tr>
<td>Device/Systems</td>
<td>Description</td>
<td>Category</td>
<td>Grade</td>
<td>Applicable</td>
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<tr>
<td><strong>Malaria diagnostic system</strong></td>
<td>A device that, when used in combination with nuclei staining reagents, counts the number of red blood cells containing protozoa and the number of normal red blood cells to inspect whether or not protozoan infections of which malaria is typical are present.</td>
<td>III</td>
<td></td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Active instrument for microwave surgical unit</strong></td>
<td>Probes, conductive cords, and their related accessories used for resection (partial resection), hemostasis and coagulation of body tissue utilizing microwaves.</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Erbium, chromium, YSGG lasers</strong></td>
<td>A laser that is used for surgical procedures, etc., and utilizes crystals consisting of erbium (Er), chromium (Cr) and yttrium-scandium-gallium-garnet (YSGG) as the substrate.</td>
<td>III</td>
<td>9-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Prosthesis for eustachian tube</strong></td>
<td>A device to be placed to maintain an appropriate lumen diameter in eustachian tube.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Heparin-coated percutaneous cardiopulmonary support system</strong></td>
<td>A heparin-coated extracorporeal circulation system that is used for periods of several days to several weeks to support cardiopulmonary function. It consists of oxygenator, blood pump, cannula, etc. Usually, the cannula is inserted and placed into the femoral artery or vein, vena cava, or the right atrium, etc., and the system is used with a dedicated driving device. This system is for single use.</td>
<td>IV</td>
<td>7-⑥,14</td>
<td>applicable</td>
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<tr>
<td><strong>Stent-graft for central circulatory system</strong></td>
<td>A device with artificial material inside, outside, or both sides of support structure (sten) or between multiple stents, that remains inside a blood vessel. This device is inserted into the blood vessel of the central circulatory system in order to maintain their patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessel or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. Some are tubular or branched.</td>
<td>IV</td>
<td>8-⑦</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td><strong>Absorbable implantable suture retention device</strong></td>
<td>An absorbable implantable device including a fixation bridge, surgical button and thread support used to ensure wider distribution of suture thread and assist the healing of the wound. Wider distribution of the tension of suture threads protects the skin or tissue from being cut by the suture thread.</td>
<td>IV</td>
<td>8-⑨</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td><strong>Vertebral body support material</strong></td>
<td>A support material with a support structure expanded and placed in a vertebral body in order to restore the vertebral height at the fracture point and form a cavity for injecting orthopedic bone cement into the vertebral body. For example, it is delivered to the fractured vertebral body by a catheter, after which the support material is expanded by a balloon catheter or by itself to support the fractured vertebral body. After the catheter is removed, the support material remains in place as a permanent implant.</td>
<td>III</td>
<td>8</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Software for central monitor with analytic capability</strong></td>
<td>A software, which configures a central monitor with analytic capability and is designed to process obtained data. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>III</td>
<td>10-④</td>
<td>applicable</td>
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<td>Description</td>
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<td>Code</td>
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<tr>
<td>Mobile analogue general-purpose diagnostic X-ray system</td>
<td>A general-purpose mobile analog radiography system, intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The mobile design allows it to operate on utility power or battery power, and the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37626010</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile analogue general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose mobile analog radiography system, intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The mobile design allows it to operate on utility power or battery power, and the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37626020</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable analogue general-purpose diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic analog radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37642010</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable analogue general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic analog radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37642020</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable digital general-purpose diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37643010</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable digital general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37643020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Stationary analogue general-purpose diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37644010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37644020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital general-purpose diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37645010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37645020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital general-purpose diagnostic X-ray system</td>
<td>A general-purpose mobile digital radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation, and its mobile design allows it to operate on utility power or battery power; the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.</td>
<td>37647010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital general-purpose integral diagnostic X-ray system</td>
<td>A general-purpose mobile digital radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation, and its mobile design allows it to operate on utility power or battery power; the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.</td>
<td>37647020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mammography combined diagnostic X-ray system</td>
<td>A system comprising a diagnostic mammography device and a general-purpose diagnostic radiography device.</td>
<td>70001000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic fluoroscopy system that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats.</td>
<td>37621010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic fluoroscopy system—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopy. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats. The X-ray generator is integrated with the system.</td>
<td>37621020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>System Type</td>
<td>Description</td>
<td>Model Number</td>
<td>Rating</td>
<td>Applicability</td>
<td>Details</td>
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<tr>
<td>Mobile analogue general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.</td>
<td>37622010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile analogue general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility)—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. The X-ray generator is integrated.</td>
<td>37622020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable analogue general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled) that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.</td>
<td>37631010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable analogue general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled)—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.</td>
<td>37631020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats.</td>
<td>37646010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Mobile digital general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats. The X-ray generator is integrated.</td>
<td>37646020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable digital general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled) that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.</td>
<td>37649010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Portable digital general-purpose integral fluoroscopic diagnostic X-ray system</td>
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<td>37649020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic fluoroscopy system that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats.</td>
<td>37679010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Stationary digital general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A general-purpose stationary diagnostic fluoroscopy system that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats. The X-ray generator is integrated with the system.</td>
<td>37679020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Linear tomography diagnostic X-ray system</td>
<td>A medical X-ray system used to produce two-dimensional cross-sectional images (tomography) on the X-ray films placed at an angle and depth that is fixed relative to the body position by adjusting the rectilinear movement of the X-ray tube, which is synchronized with irradiation but moves in the opposite direction to the recording plate and film, while irradiation is in progress. The X-ray tube moves in parallel with the film but in the opposite direction. Thereby, the shadow of the selected image remains on the film in motion, and the shadows of other images fade or disappear because of the effect of the relative displacement. This device group uses conventional technologies and the</td>
<td>37648000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>Description</td>
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<tr>
<td>Multi-directional tomography diagnostic X-ray system</td>
<td>A medical X-ray system used to produce two-dimensional cross-sectional images (tomography) on X-ray films placed at an angle and depth that is fixed relative to the body position by adjusting the fixed patterns of nonlinear movement of the X-ray tube (linear, elliptical, round, cloverleaf, or helical patterns depending on the system design), while irradiation is in progress. Thereby, the shadow of the selected image remains on the film in motion, and the shadows of other images fade or disappear because of the effect of the relative displacement. This product group uses conventional technologies and the majority of the devices have been replaced with X-ray computed tomography.</td>
<td>37660000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital angiographic fluoroscopic diagnostic X-ray system</td>
<td>A mobile digital diagnostic fluoroscopy system (moving within an X-ray imaging facility), designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses digital technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.</td>
<td>37612000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile analogue angiographic fluoroscopic diagnostic X-ray system</td>
<td>A mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility), designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses analog or analog-to-digital conversion technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.</td>
<td>37614000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue angiographic fluoroscopic diagnostic X-ray system</td>
<td>A stationary diagnostic fluoroscopy system, designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses analog or analog-to-digital conversion technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.</td>
<td>37616000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital angiographic fluoroscopic diagnostic X-ray system</td>
<td>A stationary diagnostic fluoroscopy system, designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses digital technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.</td>
<td>37623000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue mammographic diagnostic X-ray system</td>
<td>A piece of equipment designed for compression and imaging of the breast, installed in a specific location in a radiography facility or an X-ray inspection vehicle. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray films, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. This device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.</td>
<td>37630000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Applicable</td>
<td>Applicable</td>
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<tr>
<td>Portable analogue mammographic diagnostic X-ray system</td>
<td>A portable radiography system (the device can be disassembled, and moved to another location where it can be easily reassembled for use), designed for compression and imaging of the breast. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray film images, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. The breast imaging device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.</td>
<td>37632000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile analogue mammographic diagnostic X-ray system</td>
<td>A mobile radiography system (the device can be pushed by one person to various locations within a radiography facility) designed for compression and imaging of the breast. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray films, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. The breast imaging device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.</td>
<td>37671000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital mammographic diagnostic X-ray system</td>
<td>A set of equipment designed for compression and imaging of the breast, installed in a specific location in a radiography facility or an X-ray inspection vehicle. A digital mammographic system (DMS) is used for recording absorption patterns of X-ray beams that have passed through the breast on film, paper, digital, video format, or other various recording media. It is used to optimize the macroscopic evaluation of the anatomy and function of the blood and lymphatic systems in the breast. The system uses digital technology for image capture, display, and manipulation. The DMS is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of the lesion area.</td>
<td>37672000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital mammographic diagnostic X-ray system</td>
<td>A mobile radiography system (the device can be pushed by one person to various locations within a radiography facility) designed for compression and imaging of the breast. A digital mammographic system (DMS) is used for recording absorption patterns of X-ray beams that have passed through the breast on film, paper, digital, video format, or other various recording media. It is used to optimize the macroscopic evaluation of the anatomy and function of the blood and lymphatic systems in the breast. The system uses digital technology for image capture, display, and manipulation. The DMS is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of the lesion area.</td>
<td>37673000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile digital uro/gynaecological fluoroscopic diagnostic X-ray system</td>
<td>A mobile diagnostic fluoroscopy system (moving within the radiography facility) with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. The device uses digital technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or interventional procedures. The images can be viewed in both real-time and delayed formats, and has various levels of</td>
<td>37615000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Description</td>
<td>Details</td>
<td>Code</td>
<td>Type</td>
<td>Group</td>
<td>Applicable</td>
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<tr>
<td>Mobile analogue uro/gynaecological fluoroscopic diagnostic X-ray system</td>
<td>A mobile diagnostic fluoroscopy system (moving within the radiography facility) with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. It uses analog or analog-to-digital conversion technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or interventional procedures.</td>
<td>37624000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary digital uro/gynaecological fluoroscopic diagnostic X-ray system</td>
<td>A stationary diagnostic fluoroscopy system with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. The device uses digital technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or interventional procedures. The images can be viewed in both real-time and delayed formats, and has various levels of image processing and analysis capabilities.</td>
<td>37633000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary analogue uro/gynaecological fluoroscopic diagnostic X-ray system</td>
<td>A stationary diagnostic fluoroscopy system with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. It uses analog or analog-to-digital conversion technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or interventional procedures. The images can be viewed in both real-time and delayed formats, and has various levels of image processing and analysis capabilities.</td>
<td>37634000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pneumoencephalograph diagnostic X-ray system</td>
<td>A diagnostic X-ray system used in radiography of the cerebral ventricle and the subarachnoid space visualized with the sterilization gas or air injected through lumbar puncture. This product group uses conventional technologies, and the majority of the devices have been replaced with X-ray computed tomography.</td>
<td>37680000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Abdominal public health screening diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the stomach or other gastrointestinal areas of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of gastrointestinal radiographic images, using various viewing and recording media including film, paper, and fluorescent screens. The device is often used in the mobile radiography environment: it is installed in a vehicle used for medical checks, which goes from town to town.</td>
<td>37675010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Abdominal public health screening integral diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the stomach or other gastrointestinal areas of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of gastrointestinal radiographic images, using various viewing and recording media including film, paper, and fluorescent screens. The device is often used in the mobile radiography environment: it is installed in a vehicle used for medical checks, which goes from town to town.</td>
<td>37675020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Thoracic public health screening diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the chest of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment: it is installed in a vehicle used for medical checks, which goes from town to town.</td>
<td>37627010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>System Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Grade</td>
<td>Applicability</td>
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<tr>
<td>Thoracic public health screening integral diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the chests of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks, which goes from town to town. The X-ray generator is integrated with the system.</td>
<td>37627020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Thoracic and abdominal public health screening diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the chests and abdomens (stomach or other areas of the gastrointestinal tract) of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks, which goes from town to town. The X-ray generator is integrated with the system.</td>
<td>37627030</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Thoracic and abdominal public health screening integral diagnostic X-ray system</td>
<td>A diagnostic radiography system specifically designed for brief radiography of the chests and abdomens (stomach or other areas of the gastrointestinal tract) of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks, which goes from town to town. The X-ray generator is integrated with the system.</td>
<td>37627040</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental public health screening panoramic X-ray system</td>
<td>A X-ray dental diagnostic system with an extra-oral X-ray source used to generate and control X-ray beams for advanced brief dental imaging, involving the teeth, jaw, oral cavity, sinus and other maxillofacial structures of a large number of people; the device is used for panoramic imaging of signals amplified by an imaging tube with a spot camera that uses a roll film.</td>
<td>70002000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-energy X-ray bone absorptiometer</td>
<td>A single-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of a single photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured.</td>
<td>37625010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-energy integral X-ray bone absorptiometer</td>
<td>A single-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of a single photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured. The X-ray generator is integrated with the system.</td>
<td>37625020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Dual-energy X-ray bone absorptiometer</td>
<td>A dual-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of 2 types of photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured.</td>
<td>37661010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>Description</td>
<td>Detailed Description</td>
<td>Code</td>
<td>Type</td>
<td>Quantity</td>
<td>Applicability</td>
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<tr>
<td>Dual-energy integral X-ray bone absorptiometer</td>
<td>A dual-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of 2 types of photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured. Using this information, some devices can...</td>
<td>37661020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>X-ray/CT combined cardiovascular diagnostic X-ray system</td>
<td>A system combining a diagnostic X-ray computed tomography (CT) and a diagnostic cardiovascular fluoroscopy system.</td>
<td>70003000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Digital general-purpose dental intraoral X-ray system</td>
<td>A diagnostic, digital, dental (intraoral), general-purpose X-ray system used to produce and control an X-ray beam. Digital techniques are employed to record the absorption patterns of the X-ray beam used for a general dental examination or routine dental radiography associated with diagnosis and treatment (surgery and intervention) of diseases related to the tooth, jaw, and oral structures. In dental radiography, the X-ray source (X-ray tube) is placed inside the patient's mouth. This system group includes fixed, movable and portable devices, and consists of basic modular devices which can be upgraded by adding hardware or software.</td>
<td>37617000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Analogue general-purpose dental intraoral X-ray system</td>
<td>A diagnostic analog, dental (intraoral), general-purpose X-ray system used to produce and control an X-ray beam. Analog techniques or analog-to-digital conversion technology are employed to record the absorption patterns of the X-ray beam used for a general dental examination or routine dental radiography associated with diagnosis and treatment (surgery and intervention) of diseases related to the tooth, jaw, and oral structures. In radiography, the X-ray source (X-ray tube) is placed inside the patient's mouth. This system group includes fixed, movable and portable devices, and consists of basic modular devices which can be upgraded by additional hardware or software.</td>
<td>37635000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Analogue general-purpose dental extraoral X-ray system</td>
<td>A general-purpose extraoral diagnostic analog radiography system for dentistry used to generate and control X-ray beams. The device uses analog or analog-to-digital conversion technology to record the absorption pattern of X-ray beams used for general dental examination or routine dental radiography examination involving the diagnosis and treatment (surgical or interventional) of diseases of the teeth, jaw, and oral structures. The X-ray source (X-ray tube) is placed outside the patient's mouth during imaging procedures. This category includes stationary, mobile, and portable devices: the device consists of upgradable basic modules.</td>
<td>37636000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Digital general-purpose dental extraoral X-ray system</td>
<td>A general-purpose extraoral diagnostic digital radiography system for dentistry used to generate and control X-ray beams. The device uses digital technology to record the absorption pattern of X-ray beams used for general dental examination or routine dental radiography involving the diagnosis and treatment (surgical or interventional) of diseases of the teeth, jaw, and oral structures. The X-ray source (X-ray tube) is placed outside the patient's mouth during imaging procedures. This category includes stationary, mobile, and portable devices: the device consists of upgradable basic modules.</td>
<td>37667000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Analogue dental panoramic X-ray system</td>
<td>An extraoral diagnostic analog radiography system for dentistry used to generate and control X-ray beams. The device is specifically designed to produce panoramic X-ray images of teeth, jaw and oral structures. This category includes stationary, mobile, and portable devices: the device consists of basic modules that are upgradable by adding hardware or software.</td>
<td>37637000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Digital dental panoramic X-ray system</strong></td>
<td>A diagnostic digital radiography system for dentistry equipped with an extraoral X-ray source specifically designed for panoramic imaging of teeth, jaw, and oral structures; used to generate and control X-ray beams. This category includes stationary, mobile, and portable devices: the device consists of basic modules that are upgradable by adding hardware or software.</td>
<td>37640000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Analogue dental panoramic/tomographic X-ray system</strong></td>
<td>A diagnostic analog radiography system for dentistry equipped with an extraoral X-ray source used to generate and control X-ray beams used in advanced dental imaging involving the teeth, jaw, oral cavity, sinuses and other maxillofacial structures. The device uses analog or analog-to-digital conversion technology for image capture and display, and may have various image processing and analysis capabilities. This system is designed to provide the capability to produce two or more special-purpose dental radiography including linear scan, panoramic, cephalometry, linear tomography, spiral tomography, scanography, and zonography. This category includes stationary, mobile, and portable devices.</td>
<td>37668000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Digital dental panoramic/tomographic X-ray system</strong></td>
<td>A diagnostic digital radiography system for dentistry equipped with an extraoral X-ray source used to generate and control X-ray beams used in advanced dental imaging involving the teeth, jaw, oral cavity, sinuses and other maxillofacial structures. The device uses digital technology for image capture, manipulation, and display, and may have various image processing and analysis capabilities. This system is designed to provide the capability to produce two or more special-purpose dental radiography including linear scan, panoramic, cephalometry, linear tomography, spiral tomography, scanography, and zonography. This category includes stationary, mobile, and portable devices.</td>
<td>37669000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td><strong>Cephalometric diagnostic X-ray system</strong></td>
<td>A diagnostic radiography system specifically designed for the radiographic visualization and measurement of the dimensions of the human head (skull). The device may be used in various dental X-ray applications, such as orthodontics. The device is used to generate and control X-ray beams and to record the absorption patterns of X-rays passing through the head, and is intended to optimize macroscopic evaluation of the resultant image. In some devices, images can be recorded using various viewing and archive media, including film, paper, fluorescent screens, digital, and video formats. This category includes stationary, mobile, and portable devices.</td>
<td>37677010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cephalometric integral diagnostic X-ray system</strong></td>
<td>A diagnostic radiography system specifically designed for the radiographic visualization and measurement of the dimensions of the human head (skull). The device may be used in various dental X-ray applications, such as orthodontics. The device is used to generate and control X-ray beams and to record the absorption patterns of X-rays passing through the head, and is intended to optimize macroscopic evaluation of the resultant image. In some devices, images can be recorded using various viewing and archive media, including film, paper, fluorescent screens, digital, and video formats. This category includes stationary, mobile, and portable devices. The X-ray generator is integrated with the</td>
<td>37677020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td><strong>Dental digital X-ray imaging sensor</strong></td>
<td>A digital dental X-ray sensor used in the oral cavity, in combination with a general-purpose dental X-ray imaging device. The sensor consists of a CCD or other components, and comprises a sensor drive circuit and a signal processing circuit.</td>
<td>70004010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Panoramic digital X-ray sensor</strong></td>
<td>A sensor used in combination with a diagnostic digital dental X-ray imaging device that is specifically designed for panoramic imaging of teeth, jaw, and oral structures. The sensor consists of a CCD and other components, and comprises a sensor drive circuit and a signal processing circuit.</td>
<td>70004020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cephalometric digital X-ray sensor</strong></td>
<td>A sensor for a digital X-ray image processing system combined with a diagnostic X-ray system designed for visualization and size measurement of the human head (skull) using radiation. The sensor consists of the charge coupled devices (CCDs) and contains a sensor driving circuit and signal processing circuit.</td>
<td>70004030</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Limited view field X-ray computed tomography system</strong></td>
<td>A diagnostic X-ray computed tomography (CT) system equipped with a gantry designed exclusively for taking images of the area from the head to the neck or the extremities. The system is designed to have at least 1 fixed circular arrangement of multiple X-ray tubes and detectors, or designed to have an assembly where single or multiple X-ray tube(s) and detector(s) rotate around an axis at high speed within the area that the gantry can take images. Using this system, 2D or 3D images are produced. In addition, spiral CT and special radiography can be performed at multiple angles set relative to the position of the body. Various digital techniques are employed for information uptake, reconstruction and display.</td>
<td>37619000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Whole body X-ray computed tomography system</strong></td>
<td>A diagnostic X-ray computed tomography (CT) system with a sufficiently large gantry that allows imaging of any desired region of the body. It includes designs with one or more fixed annular arrays of X-ray tubes and detectors, or those with X-ray tube(s) and detector assemblies that rotate rapidly around a central axis within the gantry imaging area. It can produce 2D or 3D images; in addition, spiral CT or other special imaging can be performed at multiple specified angles in relation to body position. It uses a variety of digital technology for information capture, image reconstruction, and display.</td>
<td>37618010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Body rotational whole body X-ray computed tomography system</strong></td>
<td>A diagnostic X-ray computed tomography (CT) system used for irradiating a patient in a cone beam X-ray CT system, which is comprised of an X-ray tube and an X-ray flat panel detector, while the patient is rotated on a rotating photographing table, and collecting X-ray transmission signals related to the patient from multiple directions. The signals are processed on a computer to produce 2D and 3D images. This system can also be used to obtain a digital image as a digital radiography device (code: 70018000) that reads the output from an X-ray flat panel detector as an X-ray flat image.</td>
<td>37618020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
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<td>Applicable</td>
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<tr>
<td>Whole body electron beam X-ray computed tomography system</td>
<td>A diagnostic X-ray computed tomography (CT) system equipped with a gantry large enough to take X-rays of any part of the body. Scanning electron beam technology is used in the X-ray tube. The system mainly consists of focus and deflection coils that scan the electron beam emitted from the electron gun, a target ring to which the electron beam is led, and a detector that detects the X-rays emitted from the target ring. With the apparatus, 2D or 3D images are produced. In addition, spiral CT and special radiography can be performed at multiple angles set relative to the body position. Various digital techniques are utilized for information uptake, and reconstruction and display of images.</td>
<td>70005000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Arm type X-ray computed tomography system</td>
<td>A diagnostic X-ray computed tomography (CT) system for hard tissues such as bone and teeth, designed to acquire X-ray transmission signals from multiple angles in relation to the patient's position through the rotation of the supporting structure (arm) on which the X-ray tube and detector are mounted at both ends, and to produce 2D or 3D images by computer processing of the signals.</td>
<td>70006000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary nuclear medicine gamma camera system</td>
<td>An analog or digital diagnostic-detector based, planar (2-dimensional) nuclear medicine (NM) imaging system intended to be used in only one location within a radiographic facility or fixed in a mobile/portable imaging environment. The device uses Anger or non-Anger detection methods to record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected/orally administered radiopharmaceuticals or other radiation emitting materials.</td>
<td>40640000</td>
<td>II</td>
<td>10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td>Mobile nuclear medicine gamma camera system</td>
<td>An analog or digital diagnostic-detector based, planar nuclear medicine (NM) imaging system equipped with a motorized or electromechanical control system, which allows the user to move the device within a facility. The device uses Anger or non-Anger detection methods to record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected/orally administered radiopharmaceuticals or other radiation emitting materials.</td>
<td>40641000</td>
<td>II</td>
<td>10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td>Nuclear medicine rotating detector SPECT system</td>
<td>A single photon emission computed tomography (SPECT) stationary diagnostic system is a 3-dimensional (tomography) imaging camera-based system, used to detect, record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected/orally administered radiopharmaceuticals or other radiation emitting materials. The gantry is designed so that the detector head fitted with a collimator rotates around the patient.</td>
<td>40642000</td>
<td>II</td>
<td>10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td>Nuclear medicine annular SPECT system</td>
<td>Single photon emission computed tomography (SPECT) of a stationary diagnostic system specifically designed for tomographic imaging. It is used to detect, record, quantify and analyze radionuclide emissions produced during the decay of injected or orally administered radiopharmaceuticals or other radiation emitting materials. The position of the gantry is typically fixed; the patient's imaging table, which is controlled by computer.</td>
<td>40643000</td>
<td>II</td>
<td>10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td>Nuclear medicine positron emission tomography system</td>
<td>A positron emission tomography (PET) system specifically designed to detect, record, quantify, and analyze the pattern of 511-keV photon emissions generated by annihilation from the decay of positron-emitting radiopharmaceuticals. The device creates physiological images of 3-dimensional tomographic imaging digital sections, showing the distribution pattern of positrons emitted by the injected or orally administered radiopharmaceutical. Typically, lead collimators are used. Special software and reconstruction technology allow mapping of the metabolic patterns and metabolic rate related to the targeted physiological processes.</td>
<td>40644000</td>
<td>II</td>
<td>10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Nuclear medicine data processing system</strong></td>
<td>A data processing system specifically dedicated for nuclear medicine. The system is used for various types of filter processing, image display, clinical analysis, management of image storage, etc. The system differs from a nuclear medicine system workstation in the sense that the former has a control system for directly operating a diagnostic imaging unit. This system can deliver or receive data online or offline, and has a configuration that can provide functions such as processing, manipulating, and displaying a patient's images and information collected with the nuclear medicine imaging device.</td>
<td>70007000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td><strong>Bone absorptiometer diagnostic radionuclide system</strong></td>
<td>A diagnostic system that uses multiple radiation sources which store different types of radionuclide to produce a single radiation beam with multiple pieces of energy. This beam is passed through the anatomical area, and records the information about differences in the photon absorption rate using parameters obtained with digital images and through calculation. With this information, bone mineral density, subcutaneous fat rate, and...</td>
<td>38314000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td><strong>Radionuclide dynamic function testing equipment</strong></td>
<td>A device used to measure and record temporal variations of radioisotope concentrations in the body. Specialized devices, such as devices for thyroid uptake measurement, renograms, and radioisotope blood volume measurement, are included.</td>
<td>70008000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td><strong>Nuclear medicine rectilinear scanner system</strong></td>
<td>A rectilinear scanner is a device for detecting, recording and imaging the gamma rays emitted from a radiopharmaceutical or other radioactive materials injected or orally administered. The gantry is designed to traverse the targeting part of the body in narrow and parallel increments pre-determined by the highly collimated scintillation detector(s) (single or multiple). The detector head moves only bi-dimensionally relative to the body. The images of the detected and aggregated pattern of radionuclide distribution...</td>
<td>40645000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Nuclear medicine hand-held detector</strong></td>
<td>A hand-held non-imaging system used to detect, record, quantify, and analyze radionuclide emissions (e.g., gamma rays, alpha rays, and beta rays) by injected or orally administered radiopharmaceuticals, radiation-emitting devices or materials. The device is frequently used to monitor and detect deep vein thrombosis related to by surgical procedures requiring radionuclide positioning and some radiolabeled monoclonal antibody applications. The device is likely to have special kinds of software or auxiliary functions that are different from those of similar devices intended for radiation protection.</td>
<td>40646000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td><strong>Thyroid uptake measurement nuclear medicine system</strong></td>
<td>A diagnostic nuclear medicine system (non-imaging) designed mainly for testing and analyzing thyroid radiiodine uptake. The system can be upgraded by adding software or hardware modules to be used for various quantitative tests including a wipe test or a Schilling test, and radioimmunoassay. Generally, this system is equipped with a multichannel analyzer, a computer, a scintillation detector, a detector support device, a control console, a video display, a well counter detector, a collimator, shield materials and application software module.</td>
<td>40648000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td><strong>Nuclear medicine system workstation</strong></td>
<td>A standalone imaging workstation specifically designed to create network connection with one or more nuclear imaging devices, such as gamma camera, PET device, and SPECT device. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). It differs from an operator console in that the workstation does not have controls for the direct manipulation of the imaging device. The device allows data transfer either online or offline, and is typically situated away from the operator console. The device has a configuration in which the patient's images and information collected by the nuclear medicine system are displayed for the operator's visualization. Only...</td>
<td>40937000</td>
<td>II</td>
<td>10-②</td>
<td>applicable</td>
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<tr>
<td>System Description</td>
<td>Code</td>
<td>Level</td>
<td>ID</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td><strong>X-ray/CT combined positron CT system</strong></td>
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<td>applicable</td>
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<tr>
<td>A combined system of positron emission tomography (PET) and X-ray computed</td>
<td>70010010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>tomography (CT). The device is a 3-dimensional (tomographic) imaging device,</td>
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<td>showing the distribution pattern of positrons emitted by the injected or orally</td>
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<td>administered radiopharmaceutical: in addition, it has one or more fixed annular</td>
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<td>arrays of X-ray tubes and detectors, or X-ray tube(s) and detector assemblies that</td>
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<td>rotate around a central axis within the gantry imaging area, allowing 2-dimensional</td>
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<td>or 3-dimensional X-ray imaging. The device uses a variety of digital technology</td>
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<td>for information capture, image reconstruction, and display: by virtue of its</td>
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<td>configuration and display: by virtue of its configuration, the system is intended</td>
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<td>to correct 70010020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
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<tr>
<td>X-ray/CT combined SPECT system</td>
<td></td>
<td></td>
<td></td>
<td>applicable</td>
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<tr>
<td>A system comprises both imaging capabilities of single photon emission computed</td>
<td>70010020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>tomography (SPECT) and X-ray computed tomography (CT). The device is a 3-dimensional</td>
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<tr>
<td>(tomographic) imaging device used to detect, record, quantify and analyze</td>
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<td>radionuclide emissions (primarily gamma rays) produced during the decay of</td>
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<td>injected or orally administered radiopharmaceuticals or other radiation-emitting</td>
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<td>materials: in addition, it has one or more fixed annular arrays of X-ray tubes and</td>
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<td>detectors, or X-ray tube(s) and detector assemblies that rotate around a central</td>
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<td>axis within the gantry imaging area, allowing 2-dimensional or 3-dimensional X-ray</td>
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<td>imaging.</td>
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<tr>
<td>Positron CT combined SPECT system</td>
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<td>applicable</td>
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<tr>
<td>A system capable of performing both SPECT examination and positron CT (PET)</td>
<td>70010030</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>examination.</td>
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<tr>
<td>Nuclear medicine equipment and related system absorption compensation sealed</td>
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<td></td>
<td></td>
<td>applicable</td>
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<td>source</td>
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<td>A sealed radioisotope equipped dedicated for the correction of absorption of</td>
<td>70011000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>radiation from a diagnostic radioisotope by organs and tissues to improve</td>
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<td>quantitative capability of diagnostic imaging of the nuclear imaging system (PET</td>
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<td>or SPECT devices), thereby improving accuracy of diagnosis.</td>
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<td>Pulmonary ventilatory function</td>
<td></td>
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<td>applicable</td>
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<tr>
<td>technegas generator</td>
<td>70012000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
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<tr>
<td>Technegas is composed of ultrafine gas-like aerosols of carbon-coated technetium</td>
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<td>99-m, which enters the lungs with inhaled air, and reaches the alveolar wall. The</td>
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<td>technegas generator is a device that heats technetium 99-m together with carbon at</td>
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<td>high temperature under argon gas to form technegas by evaporation.</td>
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<tr>
<td>Mobile ultrasound imaging system</td>
<td>36208000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>A vehicle such as a van, truck or car, or a mobile storage device equipped with</td>
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<tr>
<td>at least one instance of an ultrasound diagnostic system and related devices. The</td>
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<td>device is moved to many locations by driving or being hauled by a vehicle, and</td>
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<td>used as a standalone mobile.</td>
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<tr>
<td>Ultrasound imaging system for general-purpose</td>
<td>40761000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>A general-purpose ultrasound imaging system intended for use in a wide variety of</td>
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<td>both extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The</td>
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<td>general-purpose system is intended to support a wide variety of transducers and</td>
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<td>related hardware, software and operating system software dedicated used for</td>
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<td>controlling and monitoring performance of a diagnostic ultrasound system and</td>
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<tr>
<td>related image processing, display and analytical functions.</td>
<td>40845000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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</tr>
<tr>
<td>Computer system for ultrasound imaging system</td>
<td></td>
<td></td>
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<td>applicable</td>
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<tr>
<td>A mainframe computer, a personal computer (PC) or a PC-based platform, and related</td>
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<tr>
<td>hardware, software and operating system software dedicated used for controlling</td>
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<tr>
<td>and monitoring performance of a diagnostic ultrasound system and related image</td>
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<tr>
<td>processing, display and analytical functions.</td>
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<tr>
<td>Operator console for ultrasound imaging system</td>
<td>A console for an operator functions as the main control panel for the diagnostic ultrasound system. This is equipped with hardware and software that enable display, processing and analysis of images as well as image archiving including storage and retrieval of images. It is one of the components of a diagnostic ultrasound system, and has connectivity to the general PACS, local area network, RIS or HIS system. Equipped with only the main control for direct operation, it is different from the workstation, but is generally incorporated into the integrated design of an imaging unit as seen in the mobile or portable ultrasound system.</td>
<td>40971000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Echoencephalograph</td>
<td>A graphic recorder used for recording the reflection (echo) of ultrasound in the head. With the transducer to generate and receive ultrasonic waves, the sound properties are graphically reproduced (echogram). This device is used to record the boundaries between each side of the cranium and midline structures, and detect the presence of mass lesions (e.g., brain tumor, subdural hematoma).</td>
<td>11387000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound imaging system for Obstetrics/gynaecological</td>
<td>An obstetric/gynecological ultrasound imaging system intended for use in both extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The system includes software packages supporting for various still imaging and real-time imaging related to fetal imaging, amniocentesis, and imaging of the uterus. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow. The device is also used for guiding or placing other medical devices.</td>
<td>40762000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound imaging system for mammography</td>
<td>A breast ultrasound imaging system intended for use in extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The system generally comprises a special patient table for diagnostic imaging, to obtain reproducible breast images. The system contains a software package to support a variety of still and real-time imaging of the breast, used primarily for cancer diagnosis. The device is also called an ultrasound breast-imaging system. The device is used to produce ultrasonic pulses, send the pulses to the target sites, detect ultrasonic echoes, process obtained information, and produce 2D or 3D still or dynamic images.</td>
<td>40764000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound imaging system for cardiovascular</td>
<td>An ultrasound imaging system intended for use in extracorporeal or intracorporeal (endosonographic or endoscopic) imaging procedures involving the heart and blood vessels. The system contains a software package to support a variety of still and real-time imaging of the heart, used to diagnose anatomic anomalies of the heart, and to identify blood flow characteristics and functional and anatomical problems associated with myocardial infarction. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow.</td>
<td>40763000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Grade</td>
<td>Applicable</td>
<td>Applicable</td>
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<tr>
<td>Ultrasound imaging system for bladder</td>
<td>An dedicated ultrasound imaging system used for diagnostic imaging of the bladder. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow. Information is obtained about the morphology of the bladder and lesions inside, by processing images to obtain bladder wall thickness, bladder weight, and other measurements. The system can measure urine volume in the bladder.</td>
<td>70013000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic ultrasound imaging system</td>
<td>An dedicated ultrasound imaging system used in ophthalmic diagnostic imaging. The system contains software that supports a variety of stationary or real-time imaging applications for the eye and orbit, including physical measurement and cancer treatment. The device produces ultrasonic pulses, guides the pulses to the target region, detects, and obtains bladder wall thickness, bladder weight, and other measurements. The system can measure urine volume in the bladder.</td>
<td>11389000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound pachometer</td>
<td>An ophthalmic device that uses ultrasound technology to measure the thickness of the cornea.</td>
<td>16330012</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic amplifier</td>
<td>A unit used to amplify signals transmitted from the probe of an ultrasound imaging system. This is used with an ultrasound system in the event the quality of original data transfer is lowered by the distance between the console and the imaging probe in the ultrasonic system. Signal amplification is often required in association with insertion of a small vascular ultrasound probe into the blood vessel or endoscopic insertion.</td>
<td>36370000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Axial length measuring ultrasound system</td>
<td>An ophthalmic device that uses ultrasound technology to measure axial length of the eye (distance along the axis of the eye between the anterior corneal surface and the anterior retinal surface).</td>
<td>16330022</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic ultrasound imaging/axial length measuring system</td>
<td>A multifunctional device combining the functions of ophthalmic ultrasound imaging system and axial length measuring ultrasound system.</td>
<td>16330032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound corneal thickness/axial length measuring system</td>
<td>A multifunctional device combining the functions of ultrasound pachometer and axial length measuring ultrasound system.</td>
<td>16330042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Esophageal ultrasound probe</td>
<td>A reusable or single-use ultrasound transducer assembly enclosed in a water-resistant, acoustically and electrically insulated housing that is intended to be inserted into and positioned in the esophagus by the operator. The device is also called an endoscopic ultrasound probe or an ultrasound endoscopic transducer to be used in the esophagus; the device is often incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device or a needle biopsy device. The device is composed of either a single transducer element or an array.</td>
<td>37891000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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<tr>
<td>Paranasal ultrasound probe</td>
<td>A reusable or single-use ultrasound transducer assembly enclosed in a fluid-resistant, acoustically and electrically insulated housing that is intended to be inserted into and positioned in the paranasal sinuses by the operator. The device is also called an endoscopic ultrasound probe or ultrasound endoscopic transducer to be used in the paranasal sinuses: the device is typically incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device or a needle biopsy device. The device is composed of either a single transducer element or an array of transducer elements (also called piezoelectric elements, active elements, or crystals), damping, backing, and matching materials.</td>
<td>37894000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary extracorporeal ultrasound probe</td>
<td>An ultrasound transducer assembly that is installed in the housing of an ultrasonography scanner device, such as a breast scanner, Doppler flow system, ultrasound bone absorptiometry device, or ultrasound bone densitometer; it is floor- or wall-mounted, or ceiling-mounted so that the operator can place the transducer assembly outside the patient’s body. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically.</td>
<td>40767000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Hand-held extracorporeal ultrasound probe</td>
<td>An extracorporeal diagnostic ultrasound transducer assembly that is designed to be moved manually over the intact surface of a patient’s body, during imaging applications. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device is typically used with coupling gels to ensure adequate contact with the patient. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities.</td>
<td>40768000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-vascular surgical ultrasound probe</td>
<td>A probe that is used for non-vascular surgery. A hand-held ultrasound transducer assembly designed to be positioned within a surgical site for localized intraoperative imaging applications. The device is sometimes called a surgical probe or fingertip probe. The device includes various single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities. The device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing.</td>
<td>40770002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Vaginal ultrasound probe</td>
<td>An ultrasound transducer assembly specifically designed to be positioned within the vagina either manually or under endoscopic guidance. The device includes various single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities. The device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing.</td>
<td>40771000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Rectal ultrasound probe</strong></td>
<td>An ultrasound transducer assembly specifically designed to be positioned within the rectum either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device is also known as a rectal, transrectal, or prostate probe: the device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.</td>
<td>40772000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Body orifice ultrasonic probe cover</strong></td>
<td>A protective cover designed to be put on an ultrasound probe to protect the probe from the patient’s body fluids, stains, etc., when a probe is inserted into a body orifice (e.g., transvaginal, transrectal, or transesophageal applications).</td>
<td>70015000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Intraoperative ultrasonic probe cover</strong></td>
<td>A protective cover designed to be put on a device including an ultrasound probe or gamma probe in surgical procedures to protect the probe from the patient's body fluids, stains, etc.</td>
<td>70016000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Puncture kit for ultrasonic probe</strong></td>
<td>A tool for biopsies that are performed during monitoring with an ultrasound imaging system. The kit contains covers to be placed on a device such as an ultrasound probe, and tools to guide the direction of a puncture needle. The category does not include a puncture needle.</td>
<td>70017000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
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<tr>
<td><strong>Body cavity ultrasound probe</strong></td>
<td>An ultrasound transducer assembly specifically designed to be positioned within a body cavity, either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.</td>
<td>70018000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td><strong>Bladder ultrasound probe</strong></td>
<td>An ultrasound transducer assembly specifically designed to be positioned within the bladder, either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. Also known as a bladder, or transurethral probe, the device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.</td>
<td>70019000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Stationary extracorporeal water tank coupler diagnostic ultrasound probe</strong></td>
<td>An ultrasound transducer assembly that is installed in the housing of an ultrasonography scanner device, such as a breast scanner, Doppler flow system, ultrasound bone absorptiometry device, or ultrasound bone densitometer; this may be floor-or wall-mounted, hand-held (including the desktop type), or ceiling-mounted, so that the operator can place the transducer assembly outside the patient’s body. The assembly includes a water tank, water bag, or other ultrasound medium. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically.</td>
<td>70020000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ultrasound system synchronizer</strong></td>
<td>A physiological monitoring device used as one component in a diagnostic ultrasound system. This device produces signals which can synchronize imaging acquisition and data collection with specific measurable, physiological parameters, such as the starting point of a patient’s respiratory or cardiac cycle. It is used mainly to reduce artifacts and to increase the signal-to-noise ratio in real-time ultrasonic imaging and in video imaging.</td>
<td>35460000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bone absorptiometer ultrasound system</strong></td>
<td>A device is used to perform calculation of bone mineral density and other values based on data related to the transmitted or reflected portion of ultrasonic waves after emission. The device is also called a bone densitometer. An integrated type of ultrasound transducer is used to deliver an ultrasound beam to an anatomical area of interest. Data obtained from the detection and analysis of ultrasound waves are used for estimation of bone mineral density and subcutaneous fat, or other quantitative assessment including bone fracture risks. The system generally consists of an ultrasound transducer, electronic device for detection, control panel, computer, application software, video display, and patient positioning system.</td>
<td>40779000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td><strong>Ultrasound probe positioning unit</strong></td>
<td>A unit used to position an ultrasonic transducer assembly to be inserted through an endoscope. This device is an accessory of a diagnostic ultrasound imaging system, and transmits signals that can display the position of the transducer assembly enclosed within the catheter after processing the image. This device helps to position a transducer assembly (a probe) during endoscopy, and enables movement observation after placement.</td>
<td>40786000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td><strong>Resistive magnet mammographic MRI system</strong></td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a resistive magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to the conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The MR device for mammography is typically equipped with a dedicated patient support bed for the purpose of controlling the positioning of the patient’s body to optimize visualization of the breast.</td>
<td>37611000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
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<tr>
<td><strong>Resistive magnet whole body MRI system</strong></td>
<td>A general-purpose diagnostic magnetic resonance imaging (MRI) system designed for the imaging of any targeted area of the body (whole body imaging). The system includes a resistive magnet, and can be stationary, mobile, or portable. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy, a variety of real-time imaging capabilities required in physiologically synchronized imaging, MRI mammography imaging, and other MRI-based interventions, treatments, and surgical interventions by adding software/hardware modules. The gantry treatments and surgical interventions by adding software/hardware modules. The gantry</td>
<td>37653000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Resistive magnet head/extremity imaging MRI system</strong></td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using a resistive magnet. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MRI devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real-time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.</td>
<td>37655000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Resistive magnet cardiovascular MRI system</strong></td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a resistive magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient’s body, to optimize visualization of the cardiovascular system at rest and during exercise stress.</td>
<td>37681000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Superconducting magnet mammographic MRI system</strong></td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to the conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The MRI device for mammography.</td>
<td>37609000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Superconducting magnet whole body MRI system</strong></td>
<td>A general-purpose magnetic resonance (MR) diagnostic imaging system (MRI) designed to scan any targeted area of the body (whole body imaging). The device uses a superconducting magnet, and can be stationary, mobile, or portable. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The gantry designs include closed bore, open bore, semi-open, and a variety of designs to allow the elements to be close to the patient.</td>
<td>37654000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>MRI System Type</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicable</td>
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<tr>
<td>Superconducting magnet head/extremity imaging MRI system</td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using superconducting magnet technology. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MR devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.</td>
<td>37656000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Superconducting magnet cardiovascular MRI system</td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.</td>
<td>37676000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Permanent magnet head/extremity imaging MRI system</td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using a permanent magnet. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MR devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.</td>
<td>37651000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Permanent magnet whole body MRI system</td>
<td>A general-purpose magnetic resonance (MR) diagnostic imaging system (MRI) designed to scan any targeted area of the body (whole body imaging). The device uses a permanent magnet, and can be stationary, mobile, or portable. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy, a variety of real-time imaging capabilities required in physiologically synchronized imaging, MRI mammography imaging, and other MRI-based interventions, treatment, and surgical interventions by adding software/hardware modules. The gantry designs include closed bore, open bore, semi-open, and a variety of designs to allow the elements to be close to the patient.</td>
<td>37652000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Permanent magnet mammographic MRI system</td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a permanent magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The MR device for mammography is typically equipped with a dedicated patient support bed specifically for the purpose of controlling the positioning of the patient's body to optimize visualization of the breast.</td>
<td>37659000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
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<tr>
<td>Table Title</td>
<td>Description</td>
<td>Code</td>
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<td>Applicability</td>
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<tr>
<td>Permanent magnet cardiovascular MRI system</td>
<td>A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a permanent magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.</td>
<td>37682000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>MRI system radio-frequency coil</td>
<td>Radiofrequency (RF) coils can be transmitters, receivers, or transceivers of RF pulses required for magnetic resonance imaging (MRI). The device is used to improve signal-to-noise characteristics, thereby improving image resolution. RF coils can roughly be divided into two types: volume coil (a coil surrounding the part of body to be imaged), and surface coil (a coil that is placed directly on the surface of a region of interest, or under the region and is fixed). This category includes RF coils with a variety of designs and shapes, including surface coil, phased-array coil, saddle coil, Helmholtz coil, and bird-cage coil.</td>
<td>40749000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>MRI system workstation</td>
<td>A standalone image-processing workstation that is designed to be networked with one or more magnetic resonance imaging (MRI) systems. The workstation may have any type of hardware, or any type of configuration. The MRI workstation differs from an operator console in that it does not have a control to directly manipulate the diagnostic imaging device. The device allows data transfer either on-line or off-line, and is typically situated away from the MRI operator console. The device has a configuration in which the patient's images and information collected by the MRI system are further processed to provide viewing capabilities. Only those devices capable of providing information that allows decision-making, evaluation, or diagnosis of the patient's pathologic conditions are</td>
<td>40940000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Computed radiography</td>
<td>A device that acquires an X-ray image stored in a photostimulable phosphor screen by laser beam scanning or the like; the data are then processed by a computer and converted into digital data to be output. The digital data are transmitted to an image-processing device or image recording device and used as images for diagnosis. The device uses photostimulable phosphor screens. In some cases, photo-stimulable fluorescent screen cassette may be used in combination.</td>
<td>70023000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Film-recorded digital radiography</td>
<td>An image input device that reads out medical images recorded on X-ray film to produce digital images in an indirect manner. The device, which consists of the film transport system, a stabilized light source such as a laser or halogen lamp, an optical system including a polygonal mirror, and a photoelectric conversion sensor, has higher precision and higher density readout capabilities compared to consumer electronics image readout devices. Generated digital images can include additional information such as the patient's ID, and can be stored in the image server, allowing the user to make use of the images on the medical image data system.</td>
<td>70024000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>Description</td>
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<tr>
<td>Electronically recorded digital radiography</td>
<td>A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray image intensifier/TV camera, and analog output signals are captured after analog-to-digital conversion to an image processing device to receive digital images. Digital images can be optimized by image processing technology including gamma correction and edge enhancement. The real-time capability allows video image capture. When recorded on the media, image data are also distributed through the network as needed, facilitating viewing, storing, and retrieving image data.</td>
<td>70025000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>X-ray flat panel detector-recorded digital radiography</td>
<td>A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray flat panel detector, and digital output signals are supplied to an image processing device to receive digital images. If necessary, image processing technology including gamma correction and edge enhancement are applied to digital images. Image data are either recorded on the media, or output to a server or other external devices for recording.</td>
<td>70026000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>X-ray tube housing assembly</td>
<td>A component consisting of an X-ray device for diagnostic or treatment purposes. The housing is a container made of steel, cast aluminum, or aluminum alloy and part of the interior wall is lined with lead to provide shielding against X-ray leakage occurring during patient examination or treatment procedures. This housing assembly is intended to be at ground potential, and is filled with insulated oil. This prevents electrical arcs from the high-voltage applying electrodes of the X-ray tube and high-voltage cables to surrounding objects, including the patient and operator. The housing assembly and insulated oil intended to decrease the intensity of X-ray radiation of the X-ray tube to surrounding objects.</td>
<td>35618000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary diagnostic X-ray generator</td>
<td>A generator which is an essential component of a stationary diagnostic X-ray system intended to be operated at a fixed location within a facility or an X-ray inspection vehicle. The device regulates incoming voltage and current to provide an X-ray tube with the electric power needed to produce an X-ray beam at the desired voltage (kV) and current (mA). Typically, the device may be composed of a control assembly (console) and high-voltage transformer assembly: alternatively, the device may use a mono-tank type design for high-voltage devices. Designs for transformers, constant-voltage inverters, and capacitor-discharge high-voltage devices are incorporated. Devices for treatment are excluded.</td>
<td>37604010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary integral diagnostic X-ray generator</td>
<td>A generator which is an essential component of a stationary diagnostic X-ray system operated from a fixed place in a facility or an X-ray inspection vehicle. The device adjusts the received voltage and electric current, and supplies the X-ray tube with the electricity necessary for generating X-ray beams at the required voltage (kV) and current (mA). Generally, the device consists of a control assembly (console) and a high-voltage transformer, or sometimes it incorporates a mono-tank high-voltage generator in the design. It incorporates a transformer, constant voltage, an inverter, and a capacitor discharge high-voltage generator in the design. The type for therapeutic use is excluded. An X-ray generator is integrated into the device.</td>
<td>37604020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Mobile diagnostic X-ray generator</strong></td>
<td>A X-ray generator with special size, weight, and power requirements, suitable for use in a mobile radiography system, which is intended to be operated at different locations within a facility. The device regulates incoming voltage and current to provide an X-ray beam at the desired voltage (kV) and current (mA). Typically, the device may be composed of a control assembly.</td>
<td>37605010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Mobile integral diagnostic X-ray generator</strong></td>
<td>A X-ray generator satisfying the requirements of special size, weight and power source appropriate for mobile X-ray equipment which is designed so that it can be moved to various places within the facility. The device adjusts the received voltage and electric current, and supplies the X-ray tube with that electricity necessary for generating X-ray beams at the required voltage (kV) and current (mA). It incorporates a transformer, an inverter and a high-voltage generator (capacity discharge type) in the design. Generally, the device consists of a control assembly (console), and a high-voltage transformer. However, it incorporates a mono-tank high-voltage generator in the design. This device is an essential component of mobile diagnostic X-ray equipment. The type for therapeutic use is not included.</td>
<td>37605020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Portable diagnostic X-ray generator</strong></td>
<td>A X-ray generator with special size, weight, and power requirements, suitable for use in a portable radiography system, which is intended to be disassembled, and then re-assembled after moving to different locations. The device regulates incoming voltage and current to provide an X-ray beam with the electric power needed to produce an X-ray beam of desired voltage (kV) and current (mA). Designs for high-voltage devices for this category include transformer and inverter types. Typically, the device may be composed of a control assembly (console) and high-voltage transformer assembly; alternatively, the device may use a mono-tank type design for high-voltage devices. Devices for treatment are excluded.</td>
<td>37606010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Portable integral diagnostic X-ray generator</strong></td>
<td>A X-ray generator satisfying the requirements of the special size, weight and power source appropriate for portable X-ray equipment which can be taken apart and reassembled in various places. The device adjusts the received voltage and electric current, and supplies the X-ray tube with the electricity necessary for generating X-ray beams at the required voltage (kV) and current (mA).</td>
<td>37606020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Infrared thermography system</strong></td>
<td>An electric device that produces, displays, and analyzes images or graphs of the distribution of body surface temperature in order to diagnose and evaluate various conditions and diseases. This device is also called a thermography system.</td>
<td>40803000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Thermography system operator console</strong></td>
<td>A console for an operator functions as the main control panel for a thermography system. Depending on the configuration of the system, this is equipped with hardware and software that enable display, processing and analysis of images as well as image archiving including storage and retrieval of images. It is one of the components of a thermography system, and has connectivity to the general PACS, local area network, RIS or HIS system. It is different from the workstation since it has only the main control for direct operation.</td>
<td>40972000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Powered liquid crystal thermography system</strong></td>
<td>An electric device that produces, displays, and analyzes images or graphs of the distribution of body surface temperature for the purpose of diagnosis and evaluation of clinical status or medical conditions. Sheets made from a cholesteric liquid crystal based material are enclosed in the outer layer of a blanket, pillow, mattress, or other materials placed surrounding the body. Cholesteric liquid crystals change in color with surface temperature of the body area that is in contact with the material containing cholesteric liquid crystals and the color change are analyzed macroscopically or by a software based system.</td>
<td>40798002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Microwave thermography system</strong></td>
<td>A system that utilizes microwave generation and detection technologies to produce images and graphs of body temperature distribution in order to diagnose and evaluate various conditions and diseases. This device is sometimes called a microwave thermography probe or microwave scanning system. Generally, this thermography system consists of a microwave generator (probe), a microwave detector, a thermal sensing device, an operator console, an optical camera, an electronic or computerized control software, an images</td>
<td>40802000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>LVL</td>
<td>Category</td>
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<tr>
<td>Diagnostic X-ray imaging system workstation</td>
<td>A standalone image processing workstation specifically designed for use with X-ray based diagnostic imaging system, such as digital radiography systems, X-ray computed tomography (CT) systems or fluoroscopy systems. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). The workstation differs from an operator console in that it does not have a control to directly manipulate the diagnostic imaging device. The device allows data transfer either on-line or off-line, and is typically used in X-ray CT and other modalities.</td>
<td>40935000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound imaging system workstation</td>
<td>A standalone image-processing workstation that is designed to be networked with one or more ultrasound imaging systems. The device may be regarded as a component of a picture archiving and communication system (PACS). The ultrasound workstation differs from an operator console in that it does not have a control to directly manipulate the diagnostic imaging device. The device allows data transfer either on-line or off-line, and is typically used in conjunction with ultrasound equipment.</td>
<td>40936000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrical impedance scanner</td>
<td>An electrical impedance scanner (EIS), also referred to as impedance imaging system, is a real-time 2D multi-frequency imaging system. This device is generally designed to be movable. Extremely low-voltage electric signals are sent via reference electrode attached to the body surface, which generates impedance. The device is used to map local distribution of electrical impedances by detecting the impedance values using a probe.</td>
<td>42183000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose imaging system workstation</td>
<td>A standalone imaging workstation specifically designed to use with diagnostic imaging devices, including digital X-ray, X-ray computed tomography (CT), fluoroscopy, magnetic resonance imaging (MRI), gamma camera, PET, and SPECT devices. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). Usually, the workstation differs from an operator console in that it does not have a control to directly manipulate the diagnostic imaging device.</td>
<td>70030000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Optical coherence tomography (OCT) imaging system</td>
<td>An OCT (optical coherence tomography) diagnostic imaging system which diagnostically represents the images of tissue characteristics and shapes of various sites (e.g., heart, blood vessel, abdomen, lung) using near-infrared rays, without the need to obtain tissues surgically. This system contains a software package that supports the taking of both still and real-time images, and is used to diagnose anatomic abnormalities in tissues and to examine functional and anatomic abnormalities. This system is also used to produce near-infrared rays to irradiate the target site, detect reflected light, process the data, and display the 3D image.</td>
<td>70031000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Manually-operated contrast medium injector system</td>
<td>A manually-operated mechanical system used to control the volume and speed of the contrast media infused into the blood or lymph vessels under pressure in imaging diagnosis. Generally, this system consists of a calibrated syringe, a syringe holder and a housing unit. The housing unit is placed on a table or floor stand, or permanently installed in the system.</td>
<td>40721000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered multiphase contrast medium injector system</td>
<td>A device operated by line- or battery-powered, low-or high-pressure contrast medium injector intended to allow the operator to specify a baseline contrast medium injection flow rate, to program sequential changes in the flow rate during injection, and to determine the total volume of contrast medium to be injected. The contrast medium injection system is typically used in X-ray CT, fluoroscopy/angiography, magnetic resonance imaging (MRI), ultrasound, and other examinations. Only nonmagnetic materials are used to make fixed-type contrast medium injection devices for MRI, to make the devices compatible with the MRI environment. Only devices for diagnostic imaging are included.</td>
<td>40723000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered single-phase contrast medium injector system</td>
<td>A device operated by line- or battery-powered low-or high-pressure contrast medium injector intended to allow the operator to determine the total contrast medium volume to be injected, and to specify a constant flow rate for a particular injection of the contrast medium. The system is typically used in X-ray CT, fluoroscopy/angiography, magnetic resonance imaging (MRI), ultrasound, and other examinations. Only nonmagnetic materials are used to make fixed-type contrast medium injection devices for MRI, to make the devices compatible with the MRI environment. Only devices for diagnostic imaging are included.</td>
<td>40724000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Barium enema contrast medium delivery/evacuation kit</td>
<td>A device intended to inject or discharge barium sulfate suspension (contrast medium) or air into the digestive tract during a lower gastrointestinal tract examination, consisting of a container and a tube.</td>
<td>40725000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Radioactive compound injector</td>
<td>A device intended to inject a radioactive agent or radiopharmaceutical into the subject for PET examination.</td>
<td>70032000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Brand Name</td>
<td>Code</td>
<td>Category</td>
<td>Technical</td>
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<tr>
<td>Electronic thermometer</td>
<td>A measurement device for determining the patient's body temperature. The device consists of a display unit, sensor, and other elements, and is intended to detect body temperature and convert it to some electric characteristic (e.g., resistance or voltage). These electric characteristics are processed in the electronic circuits, and the highest temperature value is retained and then digitally displayed as a temperature reading.</td>
<td></td>
<td>14032010</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Continuous measurement electronic thermometer</td>
<td>A measurement device for determining the patient’s body temperature. The device consists of a display unit, attached sensor, and other elements, and is intended to detect changes in body temperature and convert these values to some electric characteristic (e.g., resistance or voltage). These variations in the electric characteristics are processed in the electronic circuits, and are displayed continuously as temperature readings.</td>
<td></td>
<td>14032020</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Zero heat flow method thermometer</td>
<td>A thermometer intended to continuously determine the deep body temperature to the area of the body on which the measuring probe is placed. The heater, located inside the probe, is controlled in such a way that no heat flow exists between the deep tissue and the body surface, enabling temperature measurement of the deep tissue below the surface site.</td>
<td></td>
<td>70043000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Ear infrared thermometer</td>
<td>A measurement device for determining the patient's body temperature. The device is typically designed to estimate deep body (core) temperature by measuring infrared of the auditory canal. Some types of devices indicate temperature readings by directly measuring infrared radiation from the eardrum. The device may indicate corrected readings (offsets) of axillary, oral cavity, or rectal temperature readings.</td>
<td></td>
<td>17887000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Skin infrared thermometer</td>
<td>A measurement device for determining the patient’s body temperature. This device is designed to measure the infrared emissions from the skin of specific site (e.g., armpit or forehead) to estimate the temperature at the site. Some types of devices have capabilities to convert a temperature into an oral cavity or rectal temperature.</td>
<td></td>
<td>17888000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Phosphorescent/fiberoptic thermometer</td>
<td>A measurement device to measure a patient’s body temperature. This device usually utilizes a fiber-optic probe which incorporates a small temperature sensor based on physical properties (e.g., liquid crystal structure, polarization rotation) which change depending on phosphorescence decay time or other temperature.</td>
<td></td>
<td>35942000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Reusable active device connected thermometer probe</td>
<td>A device intended to connect to a thermometer, which is usually inserted into a body opening for temperature measurement. The device is intended for short-term use in body orifices (excluding the oral cavity up to the pharynx, external auditory canal up to the eardrum, and nasal cavity) and can be cleaned, disinfected, or sterilized for reuse.</td>
<td></td>
<td>37340002</td>
<td>II</td>
<td>5-⑥</td>
</tr>
<tr>
<td>Automatic electronic sphygmomanometer</td>
<td>An electronic device to be used in indirect (noninvasive) measurement of blood pressure. The device is intended for self-measurement of blood pressure at home under a physician's supervision, for the purpose of self-management of blood pressure by the user. The user must be informed of the maximum allowable cycles which are 30,000 cycles per year.</td>
<td></td>
<td>16173000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Medical electronic sphygmomanometer</td>
<td>An electronic device to be used in indirect (noninvasive) measurement of blood pressure. The device is intended for clinical measurement of blood pressure. Appropriate capabilities, automated or manual cuff pressurization, and the like are performed using a stored software. In addition to systolic and diastolic pressures, it also usually displays heart rate and mean arterial pressure. Automatic electronic sphygmomanometers are not included.</td>
<td></td>
<td>16173010</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Manually-operated electronic sphygmomanometer</td>
<td>An electronic device to be used in indirect (noninvasive) measurement of arterial blood pressure. The arm cuff pressurizes manually. The measurement reading is usually displayed on the electronic monitor.</td>
<td></td>
<td>16174000</td>
<td>II</td>
<td>10-③</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Mark</td>
<td>Applicable</td>
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<tr>
<td>Counterpressure sphygmomanometer</td>
<td>An automatic electronic sphygmomanometer that measures the change in blood volume taking place in a single finger. The device uses a cuff wrapped around a finger, which exerts counter pressure just sufficient to equal the arterial pressure (so that there is no change in arterial volume), or a sensor placed on the tip of a finger, which emits visible light and detects pulse waves, thereby detecting a subtle change in arterial volume.</td>
<td>16986000</td>
<td>II</td>
<td>10-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Central/peripheral venous pressure monitor</td>
<td>A device that measures and records invasive central or peripheral venous blood pressure measurements, or the difference between the central and peripheral venous pressures of the patient using an indwelling catheter and a pressure manometer.</td>
<td>34931000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term sphygmomanometer data recorder</td>
<td>A device intended to be carried by the patient to record long-term (24 hours) blood pressure. Recorded data are downloaded to the analyzer at the hospital for analysis.</td>
<td>36888000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ocular plethysmograph</td>
<td>A device intended for the evaluation of changes in blood flow rate in the eye. Obtained data may be used for the calculation of ophthalmic artery pressure. Some devices may contain suction or air-filled eye cups or a contact lens-type testing device with a pulse sensor or pressure sensor such as a transducer. Some devices are intended for detection and evaluation of stenosis or occlusion of carotid artery in stroke prevention programs, or evaluation of other diseases associated with the blood flow state in the internal carotid artery.</td>
<td>33384000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pressure/pulse wave testing equipment</td>
<td>A device intended to measure noninvasive blood pressure in the extremities, and to analyze by measuring once, multiple times, or simultaneously the electrocardiogram, phonocardiogram, carotid sphygmogram, finger plethysmogram, sphygmogram of the femoral artery, sphygmogram of the extremities, etc. Some include apparatuses, etc. to analyze by measuring once, multiple times, or simultaneously the electrocardiogram, phonocardiogram, carotid sphygmogram, finger plethysmogram, sphygmogram of the femoral artery, sphygmogram of the extremities, etc. Some include apparatuses, etc.</td>
<td>70045000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use intravenous line manometer set</td>
<td>A set consisting of a manometer, 3-way stopcock, and extension tubing, intended to measure central venous pressure by the water manometer method. One end is connected to the central venous catheter, and the other end is connected to the IV solution set.</td>
<td>70046002</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electronic stethoscope</td>
<td>An electronic listening device that detects and amplifies very weak internal body sounds that cannot be detected with ordinary acoustic stethoscopes. Some types of device are capable of distinguishing heart sounds and intensified sounds (e.g., blood flow passing).</td>
<td>13754000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic stethoscope</td>
<td>A portable device specifically designed for detecting blood flow using sound waves. The device usually has built-in earpieces, and uses ultrasound waves used to assess arterial and venous blood flow in patients with circulatory disturbance.</td>
<td>13756000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Magnetocardiograph</td>
<td>A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the surface of the chest in association with cardiac activity and analyze the data.</td>
<td>70047000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Magnetoencephalograph</td>
<td>A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the scalp-surface in association with neural activity and analyze the data.</td>
<td>70048000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Magnetomyograph</td>
<td>A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the surface of the body in association with muscle neural activity and analyze the data.</td>
<td>70049000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Grade</td>
<td>Applicable</td>
<td>Additional Information</td>
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<tr>
<td>Thermal dilution cardiac output unit</td>
<td>A unit for measurement of cardiac output using the indicator dilution method. A thermal indicator (cold saline solution or other solution) is injected into the blood entering the heart, and the change in temperature of the blood ejected from the heart is monitored.</td>
<td>10615010</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Thermal dilution cardiac output unit with thermal coil</td>
<td>A device designed for the cardiac output measurement using a catheter with a thermal coil. The thermal coil heats the blood entering the heart, and the change in temperature of the blood ejected from the heart is monitored using a flow-directed balloon catheter equipped with a temperature probe at its tip. The measured results are displayed on the device.</td>
<td>10615020</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Dye dilution cardiac output unit</td>
<td>A unit for measurement of cardiac output using the indicator dilution method. An indicator dye is injected into the blood entering the heart, and the change in the concentration of dye in the blood ejected from the heart is monitored using a flow-directed balloon catheter. The measured results are displayed on the device.</td>
<td>16177000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Impedance cardiac output unit</td>
<td>A unit that determines cardiac output based on measurement of thoracic impedance changes associated with cardiac activity. The measured results are displayed on the device.</td>
<td>17496000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ballistocardiograph cardiac output unit</td>
<td>A device used to record the body movement (toward the head and feet) caused by cardiac protrusion when blood is ejected by cardiac contraction. A patient is placed on a special table carefully balanced so that the transducer, which reproduces the properties of a ballistocardiogram, can sense vibrations of the body. This device is used to measure.</td>
<td>10266000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Direct Fick cardiac output unit</td>
<td>A unit to measure blood flow from the heart according to the Fick method. With this method, cardiac output is calculated as the value obtained by dividing total oxygen consumption by the difference in the oxygen content between arterial blood and mixed venous blood. This device can measure all parameters (including the mixed venous oxygen content) and display the measured values. Note: Fick’s law of diffusion: A principle that the material added in a solution tends to diffuse in the way that the concentration of the entire solution becomes uniform.</td>
<td>10814000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Thermal dilution cardiac output unit infusion/withdrawal pump</td>
<td>A dedicated pump used with a thermal dilution cardiac output flowmeter. With this pump, the appropriate pharmaceuticals or pigments are injected exactly as planned and a blood sample is collected for measuring cardiac output.</td>
<td>13320000</td>
<td>Ⅱ</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Radioisotope cardiac output unit</td>
<td>A unit to measure blood flow from the heart using the indicator dilution method. This unit injects a radioisotope into the blood flowing to the heart, and monitors the blood from the heart. The measurement results are displayed on the unit.</td>
<td>15795000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic cardiac output unit</td>
<td>A unit that measures the blood flow from the heart using the ultrasonic Doppler effect. The measurement results are displayed on the unit.</td>
<td>17190000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Arterial waveform cardiac output unit</td>
<td>A unit that determines cardiac output from the change in arterial pressure waveforms. The measured results are displayed on the device.</td>
<td>70050000</td>
<td>Ⅱ</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Pulse contour cardiac output unit</strong></td>
<td>A device that determines cardiac output continuously through pulse contour analysis. The device is used with a dedicated arterial catheter.</td>
<td>70051000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Polygraph</strong></td>
<td>A physiological recorder used to record physiological parameters including the electrocardiogram, blood pressure, electroencephalogram, body temperature, and respiration.</td>
<td>13085000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Sleep assessment device</strong></td>
<td>A device that usually records biological signals detectable during sleep, used in the evaluation of sleep disorders (e.g., insomnia, snoring, and sleep apnea). While the majority of devices are computerized, some are only used for the purpose of graphical.</td>
<td>33843000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-central circulatory angiopolygraph</strong></td>
<td>A device to examine vascular hemodynamics except in the heart.</td>
<td>70056000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electromagnetic blood flowmeter</strong></td>
<td>A device that provides confirmation and measurement of the blood flow velocity after coronary artery bypass surgery, organ transplantation and other forms of revascularization. This device utilizes invasive techniques: it uses a catheter inserted into the blood vessel or a probe encompassing the blood vessel exposed surgically without penetrating the vascular wall. It is also called an EM flowmeter.</td>
<td>10431000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ultrasonic blood flowmeter</strong></td>
<td>A noninvasive, or invasive ultrasonic Doppler device for blood flow measurement. Intended for the identification of various blood flow disorders, e.g., thrombosis, stenosis, etc.</td>
<td>10432000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Doppler blood-flow measurement ultrasound system</strong></td>
<td>A portable or stationary ultrasonic device that does not produce 2-dimensional or 3-dimensional images, and is intended to be used for determining various blood flow related parameters of the heart, artery, or vein. The device is used to output audible data, or display the Doppler shift as a function of time, allowing comparison of normal and abnormal blood flow patterns for diagnosis. The continuous wave Doppler and pulsed.</td>
<td>40759000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Laser blood flowmeter</strong></td>
<td>A device that measures blood flow velocity using laser techniques, noninvasively or invasively, to identify impairment of blood flow (e.g., thrombus, stenosis, mechanical injury), and supports evaluation of the degree of the impairment.</td>
<td>16903000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Magnetic resonance blood flowmeter</strong></td>
<td>A device that applies a quantitative method to check the adequacy of blood flow in patients with symptoms of peripheral vascular disease. This device senses a magnetic field around the blood vessel.</td>
<td>18019000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-indwelling blood flow transducer</strong></td>
<td>A device for measuring blood flow externally (extravascularly). The device is used together with a blood flowmeter. The device may measure the blood flow either inside the heart or over the outside of a blood vessel (formed as an open circle which is slid over the vessel, available in different diameters to fit the size of individual blood vessel). Some devices employ ultrasound or electromagnetic technology.</td>
<td>31657000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Spinal fluid pressure monitor</strong></td>
<td>A device to measure direct spinal fluid pressure in the patient concerned when necessary as a result of hospitalization, treatment or diagnosis. It is a mechanical measuring device.</td>
<td>31319010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electronic spinal fluid pressure monitor</strong></td>
<td>A device to measure direct spinal fluid pressure in the patient concerned when necessary as the result of hospitalization, treatment or diagnosis. It is an electronic measuring device.</td>
<td>31319020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Standard</td>
<td>Applicable</td>
</tr>
<tr>
<td>---------------</td>
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<tr>
<td>Intrauterine pressure monitor</td>
<td>A device used during treatment or diagnosis to measure directly intrauterine pressure which influences a patient.</td>
<td>33727000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Esophageal pressure monitor</td>
<td>A device used for the diagnosis related to the esophageal function and postoperative evaluation in esophageal manometry. This device may be the main component of the esophageal stethoscope.</td>
<td>35248000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use pressure transducer</td>
<td>A device used to convert pressure into electric signals to display on the base unit. The device is intended for single-use.</td>
<td>35927000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable pressure transducer</td>
<td>A device used to convert pressure into electric signals to display on the base unit. The device is reusable.</td>
<td>14119000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable pressure transducer dome</td>
<td>A device (dome) to be connected with a pressure transducer to form a measurement system, for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. Some types of device incorporate a stopcock and flushing device. The pressure transducer is influenced by pressure in the medium that enters the measurement system, thereby creating signals. The device is intended for single-use.</td>
<td>37312000</td>
<td>II</td>
<td>2-①,2-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use pressure transducer dome</td>
<td>A device (dome) to be connected with a pressure transducer to form a measurement system, for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. Some types of device incorporate a stopcock and flushing device. The pressure transducer is influenced by pressure in the medium that enters the measurement system, thereby creating signals. The device is intended for single-use.</td>
<td>37257000</td>
<td>II</td>
<td>2-①,2-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Fascial pressure monitor</td>
<td>An internal pressure meter that measures intrafascial pressure.</td>
<td>70056000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Barostat</td>
<td>A device that pumps air into a balloon inserted into the gastrointestinal tract including the esophagus, stomach, small intestine, large intestine, and rectum at a constant rate to measure the pressure changes associated with; the causes of internal pressure data, and gastrointestinal motility, measurement is made using the open-chip method.</td>
<td>70057000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Infusion pump</td>
<td>A device that pumps a constant volume of water into a catheter in manometry of the gastrointestinal tract including esophagus, stomach, small intestine, large intestine, and rectum, when the pressure is measured with a transducer. In monitoring esophageal and gastrointestinal motility, measurement is made using the open-chip method.</td>
<td>70058000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic tonometer</td>
<td>A device specifically designed for intraocular pressure measurement.</td>
<td>16809000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Tonograph</td>
<td>A device for recording a graph of the change in intraocular pressure as the applied force is varied. A variety of tension recording systems are used, such as an air-puff tension recording system, which records deflections of the cornea in reaction to a puff of pressurized air, and an applanation tonometry recording system and the like, which records the force necessary to impress or flatten the cornea surface.</td>
<td>35399000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use applanation tonometer measuring prism</td>
<td>A single-use sterile device designed to be used in combination with an applanation tonometer for evaluation of the contact area of the cornea.</td>
<td>70059000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Standard</td>
<td>Applicability</td>
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<tr>
<td>Phonocardiograph</td>
<td>A device that records heart sounds on the body surface. Vibrations caused by cardiac activity are transmitted to the body surface via the organs and tissues and are detected by a microphone. The vibrations are processed with an electric filter, and the sound properties of the phonocardiograms are obtained. The device is used to evaluate lower frequencies (atrial or ventricular gallop) and higher frequencies (mitral regurgitation or ventricular septal defect). Usually, one type of this device may record subsonic frequencies.</td>
<td>13017000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Fetal heart phonodetector</td>
<td>A device that detects fetal heart sounds sonically, utilizing ECG with a function to capture heart sounds.</td>
<td>35067000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic fetal heart detector</td>
<td>A device that uses ultrasonic waves to transduce the data of fetal heartbeat into audible sound.</td>
<td>35068000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart rate monitor</td>
<td>A device that measures and displays a patient's heart rate (beats/min). This device is usually used during exercise stress testing.</td>
<td>35197000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pulse rate meter</td>
<td>A device that measures the pulse rate per minute when a change in intravascular pressure, which is generated when the blood is pumped out to the aortic root by cardiac contraction, propagates itself peripherally. Measurement is made using methods related to pressure, photoelectrical strain gauge, and impedance.</td>
<td>70061000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart sound transducer</td>
<td>A device intended to be placed on the chest to detect sounds coming from the heart valves.</td>
<td>33315000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use body orifice thermometer probe</td>
<td>A device intended to connect to a thermometer, which is usually inserted into a body opening for temperature measurement. The device is intended for short-term use in body orifices (excluding the oral cavity up to the pharynx, external auditory canal up to the tympanic membrane, and urethra up to the orifice of the prostate).</td>
<td>35254002</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroacoustic transducer</td>
<td>A device used to detect oscillations that are generated by the activity of the heart and transmitted to the body surface via organs and tissues. The device generally consists of a microphone and signal-transmitting components. The device is used together with other devices including a phonocardiograph.</td>
<td>37336000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasound probe for cystometer</td>
<td>An ultrasonic probe used with a cystometer utilizing ultrasound technology. This device generates ultrasounds of relatively low frequencies.</td>
<td>37804000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Cystometer</td>
<td>A device used for examination of the bladder to obtain measurement data related to pressure and volume. These data are used for diagnostic evaluation of the neuromuscular mechanism of the bladder. It can also measure postvoid residual volume. The operation modes include mechanical, ultrasonic, or combined modes.</td>
<td>11111000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Partial-body plethysmograph</td>
<td>A device that measures and records the change in the volume of the organ, the body part, or the limb. This is also used to record the blood volume present in the area examined and the volume passing through the area. Many measuring techniques may be employed with this device.</td>
<td>13056000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Complexity</td>
<td>Applicability</td>
</tr>
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</tr>
<tr>
<td>Urodynamic measurement system</td>
<td>A system intended for diagnosis and testing of urinary bladder function. The device is used to identify causes of micturition abnormalities (including incontinence). The device is useful for the diagnosis of conditions including neurogenic bladder, urinary stress incontinence, urinary obstruction, and a spastic urinary sphincter. A diagnostic urodynamic study consists of uroflowmetry (measurement of urinary flow rate), urethral pressure profilometry, and other tests.</td>
<td>14307000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Portable penile tumescence data recorder</td>
<td>A device that monitors the erection of the penis (erection tendency). The patient carries the device and records the erectile function (e.g., length, thickness, duration). The recorded data are used to diagnose penile dysfunction (e.g., impotence).</td>
<td>33890000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Whole body plethysmograph</td>
<td>A device that measures and records volume changes in the body. The device is usually constructed of metal, plastic, and glass, and is often used for pulmonary function studies. The unit consists of an airtight chamber in which the patient is placed, and a spirometer, which is used to determine lung volume changes of the patient and airway resistance.</td>
<td>35242000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Compartmental pressure monitor</td>
<td>A device used to measure increased intramuscular pressure caused by compartmental syndrome. Compartment syndrome is disease attributable to swelling in the muscular compartment and the myelin sheath.</td>
<td>35997000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pressure amplifier</td>
<td>An amplifier used to measure pressure (e.g., blood pressure). This device group may reflect conventional techniques.</td>
<td>36748000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Phonocardiograph/pulse wave unit</td>
<td>A heart sound/pulse wave unit to obtain a recording of heart sounds and pulse waves by connecting to the electrocardiograph or the electrocardiographic analysis system. In order to comprehensively diagnose cardiac function, this unit simultaneously records the electrocardiogram, combined with the carotid pulse wave, apex beat, digital pulse volume, phonocardiogram, etc.</td>
<td>70062000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose electrocardiograph</td>
<td>A device used to detect, register, and record electric signals generated as a result of activities of the heart, and to reproduce such signals (voltage versus time) as an electrocardiogram (ECG) for later use. The ECG is usually reproduced in the form of a printout; however, in some types of device, it is displayed on a monitor, or using digital media. The device may have other capabilities (e.g., single channel or multi-channel recording, data storage, interpretation, tests that involve passive or active participation of the patient).</td>
<td>11407010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term electrocardiographic data recorder</td>
<td>A device that records cardiac activity over 24 hours. During recording, the device is connected to and carried by the patient. Signals are stored on a cassette tape (magnetic tape) or digital media (non-movable media). Recorded data are analyzed at the hospital.</td>
<td>35162000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>ECG recorder with real-time analysis</td>
<td>A device that performs real-time analysis of measured electrocardiogram (ECG) signals, and records abnormal waveforms present on ECG.</td>
<td>70063000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Certification</td>
<td>Applicability</td>
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<td>------------------------------------------------------</td>
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</tr>
<tr>
<td>Holter analyzer</td>
<td>A device used to analyze a patient’s long-term (usually, 24-hour) cardiac activity, previously recorded using an ambulatory monitoring device connected to the patient. The device is used with an ambulatory long-term electrocardiogram (ECG) monitoring device.</td>
<td>36827000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Computer for electrocardiogram interpretation</td>
<td>A dedicated computer with special cardiac software installed. It is used to read waves obtained in the electrocardiograph (ECG). The pre-specified pattern recognition technology is utilized to read the waves. Electrocardiographic signals registered are compared with the pre-defined diagnostic criteria.</td>
<td>34972000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac stress exercise monitoring system</td>
<td>A stress exercise device designed to record electrocardiogram (ECG) signals from electrodes placed on the patient’s limbs and chest while the patient exercises in varying amounts, using a treadmill, ergometer, or other device. The device usually analyzes recorded data, displays results, monitors functions, controls patient workload and prints out results, thereby providing physicians with a representation of general electrical activity of the heart (including heart rate).</td>
<td>36145000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>ECG telephonic transmission equipment</td>
<td>A device that uses communication methods (e.g., phone) to transmit electrocardiogram (ECG) signals measured on the patient.</td>
<td>70064000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Apex cardiograph</td>
<td>A device used to record pulsations at the left ventricular apex in the precordium. This device senses motion (vibration) of the soft tissues within the intercostal spaces with a non-invasive transducer, and reproduces the properties on the apex cardiogram. It is used to assess left ventricular function.</td>
<td>10164000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>His bundle detector</td>
<td>A device to detect disorders of impulse conduction in the bundle of His (atrioventricular) from the atrium to the cardiac ventricle. The bundle of His is a collection of electrical fibers in the heart that conduct the electrical impulses that regulate the heartbeat.</td>
<td>12009000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Impedance cardiograph</td>
<td>An electrocardiograph used to record variations in chest electric impedance generated by myocardial activity. Usually, detection is performed on the body surface. A graph of sequential variations in impedance (impedance cardiograph) is recorded. This electrocardiograph is used to examine myocardial activity to diagnose specific cardiac abnormalities and to detect trends and variations in cardiac function.</td>
<td>12103000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Vector cardiograph</td>
<td>An electrocardiograph (ECG) device used to record a series of changes in the magnitude and direction (vector) of the potential in a complete cardiac cycle. Some devices display electric signals as a loop (representing the 2-dimensional projection of the tip of the ECG).</td>
<td>14345000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiokymograph</td>
<td>An electrocardiograph that records heart wall motion (mainly motion of the left ventricular anterior wall) on an amplitude vs. time graph (heart kymograph). The device utilizes a transducer (e.g., a flat coil) fixed to the chest by a strap as a part of heart.</td>
<td>16522000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ischemia monitoring system module</td>
<td>A small dedicated device used for measurement of ischemia (a decrease in blood supply to a part of the body) detected through connected cables/lead codes including 12-lead ECG cables placed on the body based on the vector method. It is designed to work as a part of exercise stress testing devices.</td>
<td>37249000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Exercise stress test computer</td>
<td>A dedicated computer used to interpret various physiological parameters, wave forms obtained during stress testing (exercise stress testing), and a special software package is installed in it. Using pre-specified pattern recognition technology, signals are transmitted from exercise testing devices, such as an ergometer connected to the computer.</td>
<td>35447000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiograph amplifier</td>
<td>An amplifier used in conjunction with an electrocardiograph (ECG). This device group may reflect conventional techniques.</td>
<td>36719000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Function Description</td>
<td>Code</td>
<td>Grade</td>
<td>Application</td>
<td>Notes</td>
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<tr>
<td>Multi-function electrocardiograph</td>
<td>A device that records and displays electrocardiograms either manually or automatically, and is also capable of analyzing recorded electrocardiograms, recording, and displaying.</td>
<td>11407020</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>ECG and blood pressure Holter recorder</td>
<td>A device that records electrocardiograms and noninvasive intermittent blood pressure measurements continuously, for a long period of time.</td>
<td>70066000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac event recorder</td>
<td>A device that is carried or worn by the patient, and records or transmits cardiac activity (e.g., electrocardiogram and heartbeat) upon activation by the patient. Recorded data are analyzed using an analyzer or computer with special software at the medical institution.</td>
<td>70067000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiograph with ultrasound diagnostic system</td>
<td>A system integrates an electrocardiograph, which is capable of recording the standard 12-lead electrocardiogram (ECG) and analyzing the ECG, and devices such as a general-purpose ultrasound diagnostic device. In addition to ECG recording and analysis capabilities, the device is capable of ultrasound diagnosis of the abdomen, the mammary gland, the thyroid gland, and the chest.</td>
<td>11407030</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroencephalograph</td>
<td>A device used to record potential changes that are generated as a result of electrical activity of the brain, usually detected on the surface of the scalp. Electric signals are transmitted to the recorder from leads placed on the scalp and the ear lobes, reproducing their characteristics as an electroencephalogram (EEG). The device is used to study brain activity.</td>
<td>11467010</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Visual evoked response stimulator</td>
<td>A stimulation device that provides visual stimulation to the eye of a patient (e.g., pattern change). Usually, it is either an optical stimulator in which the stimulus is transmitted through an optical system to the eye or a direct-view stimulator in which the stimulus is presented directly to the eye.</td>
<td>35373000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Auditory evoked response stimulator</td>
<td>A stimulation device that provides appropriate stimulation of the auditory system. The device is used for the measurement of evoked responses, activation of the electroencephalogram (EEG), and other purposes.</td>
<td>35368000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Fetal auditory evoked response stimulator</td>
<td>A stimulation device that uses acoustic stimuli to evaluate fetal health. The device, which consists of a sound source providing vibroacoustic pulse stimulation, is placed on the abdominal region of the pregnant woman corresponding to the top of the head of the fetus. The device is used in prenatal tests or monitoring of the labor to evaluate the condition of the fetus based on the change in fetal heartbeat, acid-base balance and other factors.</td>
<td>36159000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroencephalographic spectrum analyzer</td>
<td>A device used to display frequency components of electroencephalogram (EEG) signals and power spectral density.</td>
<td>35777000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Brain electric activity mapping equipment</td>
<td>A device used to analyze and display the action potential distribution map of measured electroencephalogram signals.</td>
<td>11467020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Magnetic stimulator</td>
<td>A device that uses magnetic fields to stimulate certain areas of the central or peripheral nervous system.</td>
<td>36902000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Title</td>
<td>Status</td>
<td>Applicable</td>
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<tr>
<td>Scalp electroencephalographic electrode</td>
<td>A conductor placed in the scalp to record changes in electrical potential in various areas in the brain. This electrical activity is generally recorded by an electroencephalograph.</td>
<td>11440002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term electroencephalograph data recorder</td>
<td>A device carried by the patient for long-term electroencephalogram (EEG) recording (24 hour-recording). The data are deciphered by the long-term EEG analysis device for detailed assessment.</td>
<td>35163000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Epilepsy alarm</td>
<td>A device that sends out an alarm signal as a warning for signs of epileptic seizure.</td>
<td>36693000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroencephalograph amplifier</td>
<td>An amplifier used in the electroencephalograph (EEG). This device group may reflect conventional techniques.</td>
<td>36740000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term recording electroencephalographic analyzer</td>
<td>A device used to analyze the long-term neural activity (usually brain activity for 24 hours) previously recorded with a recording device that is attached to a patient and carried by the patient.</td>
<td>36901000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electromyograph</td>
<td>A graphic recorder that is used for the measurement and recording of the intrinsic electrical potential of skeletal muscle. The device is usually used in the clinical diagnosis of myopathy, to evaluate muscle weakness, and to determine whether weakness is related to the muscle itself or nerves connected to the muscle.</td>
<td>11474000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electromyograph electrode</td>
<td>A conductor that is inserted into the muscle or nervous tissue to detect bioelectric signals. These devices are usually needle electrodes. The electrical activity detected by the device is generally called an electromyography (EMG).</td>
<td>11441002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrically-evoked response stimulator</td>
<td>A device used to provide electrical stimulation using skin electrodes to measure the evoked response.</td>
<td>32516000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Facial nerve stimulator</td>
<td>A device used to test the viability of facial nerve branches during the diagnostic and clinical assessment of facial paralysis (e.g., Bell's palsy), or when facial nerves have been damaged due to surgical procedures. Some devices can test muscle contractility independent of innervation. During facial surgery, the device is useful in locating nerves under exposed tissue and preventing accidental damage to facial nerve branches.</td>
<td>35724000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Somatosensory nerve electrical stimulator</td>
<td>An electrical stimulator used to apply precisely timed and repeatable stimuli to the peripheral nerves. The device is usually a multiple-channel external stimulator that uses external surface electrodes or invasive (i.e., needle) electrodes. The device is used for evoked-potential procedures and also for other research procedures (e.g., functional)</td>
<td>35726000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Diagnostic neuromuscular electrical stimulator</td>
<td>A stimulator designed to apply stimuli to a peripheral region while monitoring the response in a different peripheral region. The device usually has simpler design and capabilities than a treatment neuromuscular stimulator does. Most diagnostic neuromuscular stimulators use external electrodes (e.g., hand-held bipolar electrodes, ring electrodes, and needle electrodes) to stimulate highly localized areas. These devices are used to stimulate a peripheral nerve or muscle during motor-nerve conduction studies (e.g., posterior tibial nerve) or sensory-nerve conduction studies (e.g., ulnar nerve), for diagnostic or therapeutic stimulation.</td>
<td>35729000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Rating</td>
<td>Applicable</td>
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<tr>
<td>Cardiac electrophysiology stimulation system for diagnostic</td>
<td>A programmable stimulator that delivers precisely timed electrical impulses to the heart at the time of spontaneous rhythm or pacing. This device can be used in asynchronous or synchronous mode to provide various stimulations. For pacing, a wide range of cycle lengths (usually 150 to 1500 ms) can be applied. The device is used for cardiac physiological testing, such as for determining the function of each component of atrioventricular conduction, assessing factors necessary to induce and stop tachycardia, and the sinus node function.</td>
<td>35974000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric stimulator needle electrode</td>
<td>A conductor used to apply electrical current to tissue. In using, a pair of cathode and anode is needed. These are usually called needle electrodes.</td>
<td>34374102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Subcutaneous stimulator probe</td>
<td>A subcutaneous probe specifically designed to be used with a stimulator.</td>
<td>36957002</td>
<td>II</td>
<td>6,6-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electromyograph amplifier</td>
<td>An amplifier intended to be used to perform electromyography (EMG). Devices in this category may reflect conventional technology.</td>
<td>36728000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Physiological signal conditioner</td>
<td>A device used to record, process, or display biological signals (e.g., integrator and differentiator). Only devices intended to be used off-line are included.</td>
<td>32520000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Auditory evoked response audiometer</td>
<td>An electronic acoustic device used to evaluate the activity of the auditory nervous system in response to an acoustic signal at the ear. Signals (detected via scalp electrodes) may be measured only by computer averaging and signal processing technology.</td>
<td>35747010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Evoked response computer</td>
<td>A device that measures biological signals generated in response to stimuli, and performs averaging and other data analysis processing.</td>
<td>70068000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Obstetric perinatal physiologic data analyzer</td>
<td>A device used during labor to analyze electronic signal data obtained from a maternal/fetal monitor. With this device, the condition of the fetus can be clinically diagnosed, and recommendations are provided regarding delivery management and clinical intervention. This device may be equipped with a signal analyzer, an indicator and an electronic interface with another device.</td>
<td>32626000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Obstetrical prenatal physiologic data analyzer</td>
<td>A device that uses a microcomputer to assess and report fetal growth based on information obtained from ultrasonography. A hand-held pocket-type with a built-in computer (a programmed calculator) is available. Data are entered manually in this type. On the other hand, a large desk-top type can provide hard-copy reports, enter data automatically, and store reports for later data search and review.</td>
<td>43007000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Reg. Status</td>
<td>Applicable</td>
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<tr>
<td>Cystoscopic electrode</td>
<td>A conductor to record the electrical activity of the bladder. It is placed in direct contact</td>
<td>11436000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
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<td>with the bladder so that it can stimulate the bladder to generate the electrical activity.</td>
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<tr>
<td>Electroglottograph</td>
<td>A graphic recorder to record changes in electric potential or impedance caused by vocal</td>
<td>16034000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>cord movement during respiration and speech. An appropriate sensor is utilized. It is used</td>
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<td>in dysphonia treatment to assess the severity of vocal cord obstruction and to examine the</td>
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<td>pharyngeal mechanism.</td>
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<tr>
<td>Cardiac imaging system</td>
<td>A device that captures and analyzes cardiac image signals from an ultrasound imaging system.</td>
<td>70069000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>With this device, chamber volume calculation, ventricular wall motion analysis and coronary</td>
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<td>stenosis analysis can be performed.</td>
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<tr>
<td>Electronystagmograph</td>
<td>A graphic recorder that is used to detect electrical potential generated by eye movement.</td>
<td>11479000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td></td>
<td>The device is equipped with electrodes for each eye to allow measurement of both eyes</td>
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<td>simultaneously and for the forehead (for multi-channel recording). Electrode positions</td>
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<tr>
<td>Electroretinograph</td>
<td>A graphic recorder of the changes in electrical potential on or near the surface of the</td>
<td>11482000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>cornea when compared to a reference point on the body, following stimulation of the retina by</td>
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<td>light (e.g., flashes of white light). These recorders include a primary electrode (generally</td>
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<td>gold, platinum, or silver) and a reference electrode which are placed on the</td>
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<tr>
<td>Esophageal electrode</td>
<td>A conductor used to stimulate contraction of the esophageal muscle.</td>
<td>35037000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
</tr>
<tr>
<td>Fetal scalp electrode</td>
<td>An electric signal conductor that is placed directly on the scalp of the fetus in the uterus,</td>
<td>35038002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td></td>
<td>to monitor fetal vital signs. They are usually spiral electrodes.</td>
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<tr>
<td>Visual evoked response</td>
<td>A device used to measure the changes in bioelectrical potentials evoked by visual stimuli</td>
<td>70071000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>computer</td>
<td>(e.g., brightness change or graphical change).</td>
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</tr>
<tr>
<td>Electrooculograph</td>
<td>A device is intended to record potential difference between the retina and cornea during</td>
<td>11480000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
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<td>eye movement in response to visual stimuli. These devices may include surface electrodes,</td>
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<td></td>
<td>N/A</td>
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<td></td>
<td>which are placed at the inner and outer canthi of each eye, and an amplifier that boosts</td>
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<tr>
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<td>the bioelectrical potential. Some types of recorder have a built-in personal computer, or</td>
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</tr>
<tr>
<td>Physiological signal</td>
<td>An amplifier to adjust the signal level and impedance between two or more medical devices</td>
<td>352521000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>amplifier</td>
<td>that transmit biological signals.</td>
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<tr>
<td>Block monitoring peripheral</td>
<td>A type of electrical nerve stimulator that stimulates the nerves to assess the adequacy of</td>
<td>35722000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>nerve electrical stimulator</td>
<td>surgical neuromuscular block (e.g., ulnar nerve, facial nerve, lower leg nerve) and the</td>
<td></td>
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<td></td>
<td>N/A</td>
</tr>
<tr>
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<td>disappearance of the neuromuscular block during the recovery period. The device is</td>
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<td>battery-powered or line-powered, and usually the following 4 types of stimulation mode.</td>
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<tr>
<td>Patient monitoring system</td>
<td>A system consisting of various devices used for detecting, processing and displaying the</td>
<td>37595000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
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<td>vital signs of multiple patients at the same time. The system is designed to emit a signal</td>
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<td>or an alarm visually or audibly in the event any harmful condition is detected and</td>
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<td>recorded; this provides healthcare practitioners with a high-level monitoring system. It</td>
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<td>collects the signals from the patients using numerous monitors and other devices (on both</td>
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<td>sides of the body).</td>
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<tr>
<td>Central monitor</td>
<td>A unit designed to collect, process, or display vital signs and other patient data from a</td>
<td>38470002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
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<td>single or multiple bedside monitoring units. The unit is designed to actuate visual or</td>
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<td>audible signals/alarms if adverse conditions are recorded. The device is usually placed</td>
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<tr>
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<td>within an intensive care unit or the central patient monitoring station in a cardiology.</td>
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<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Type</td>
<td>Rate</td>
<td>Applicable</td>
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<tr>
<td>Breathing frequency monitor</td>
<td>A noninvasive device that measures respiratory rate. Some types of device have additional capabilities such as respiratory volume measurement or alarm notification.</td>
<td>12662000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ventilation monitor</td>
<td>A device that continuously monitors the breathing circuit by means of various respiratory parameters in the respiratory cycle, such as respiratory rate, pressure, flow rate, and lung volume. Respiratory rate indicator and I:E ratio indicator may be equipped. The device gives an alarm at onset of abnormal ventilatory function</td>
<td>12678000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Noninvasive blood pressure monitor</td>
<td>A device that measures blood pressure noninvasively outside the patient's body, and processes and displays the data. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered. Some types of device use an external transducer.</td>
<td>31681000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood-pressure alarm</td>
<td>A device that monitors a patient's blood pressure and sends out alarm signals in the event it exceeds a pre-defined limit.</td>
<td>31691000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Invasive blood pressure monitor</td>
<td>A device that measures blood pressure invasively in an artery, and processes and displays the data. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered.</td>
<td>31692000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Multiparameter monitor</td>
<td>A unit that collects data of several monitoring parameters using an embedded function kit, module, or other devices and displays the data by bed or by patient. The bedside unit can be connected to the central monitor; it can also be operated alone. Monitoring parameters include electrocardiogram (ECG), blood pressure, body temperature, cardiac,</td>
<td>33586002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>ST-segment monitor</td>
<td>A device that measures and displays the ST-segment of the electrocardiogram (ECG) signals.</td>
<td>34115000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Respiration monitor</td>
<td>A device intended to monitor the respiratory function of the patient. The device measures the flow rate of an inhaled or exhaled breath, and airway pressure (Paw). Some types of device measure carbon dioxide (CO2), oxygen (O2) and esophageal pressure (Pes).</td>
<td>35194002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiographic monitor</td>
<td>A device that processes and displays the patient's electrocardiogram (ECG). Some types of device display heart rate. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered.</td>
<td>35195000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroencephalographic monitor</td>
<td>A device that processes and displays electric signals generated in the brain, and presents them, typically in the form of an electroencephalogram (EEG).</td>
<td>35196000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrocardiographic module</td>
<td>A type of plug-in module intended for use with a multiparameter monitor and used for the detection and recording of electrocardiogram (ECG) signals; those with arrhythmia analysis functionality are excluded.</td>
<td>36349002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Module Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Quantity</td>
<td>Applicability</td>
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</tr>
<tr>
<td>Respiration module</td>
<td>A type of plug-in module intended for use with a multiparameter monitor, and used to measure the flow rate of an inhaled or exhaled breath, and airway pressure (Paw). Some types of device measure carbon dioxide (CO2), oxygen (O2) and esophageal pressure (Pes).</td>
<td>70076000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Invasive blood pressure module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for measurement of blood pressure (at single or multiple sites) using a pressure transducer directly inserted into a blood vessel via a catheter.</td>
<td>36550000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Noninvasive blood pressure module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for measurement of blood pressure with a cuff wrapped around the arm or leg (noninvasive method).</td>
<td>36551000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Carbon dioxide module</td>
<td>A type of plug-in module usually intended for use with a multimodal-monitor, and used for measurement of carbon dioxide (CO2) content in an exhaled breath. Carbon dioxide content can be measured from the mainstream or sidestream.</td>
<td>36552000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Multifunction module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement and monitoring of two or more functional indicators (e.g., electrocardiogram [ECG], respiratory rate, temperature, blood pressure, pulse or oximetry).</td>
<td>36553000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pulse oximeter module</td>
<td>A type of plug-in module usually intended for use with a multimodal-monitor, and used for the percutaneous measurement of oxygen saturation in blood (SpO2) by photodetection with a special probe. Light emitted from the light-emitting diode (LED) reaches arterial blood as received by the detector and is measured by the principle of spectrophotometry.</td>
<td>36554000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac output module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement of cardiac output (blood volume pumped out from the heart per minute). The device is usually used for bedside monitoring.</td>
<td>36561000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Body temperature module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement and monitoring of the patient’s body temperature (single or multiple sites). Usually, a probe (cutaneous or rectal) is used for measurement.</td>
<td>36562000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Transportable multiparameter monitor</td>
<td>A monitoring unit specifically designed for use while the patient is in transit (from some other place to hospital, from hospital to another hospital, or to another department within the hospital). Parameters that can be monitored include electrocardiogram (ECG), blood pressure, temperature and pulse oximetry. This device can be used as an ordinary bedside unit.</td>
<td>36872000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Multi-gas module</td>
<td>A type of plug-in module usually intended for use with a multimodal-monitor, and used for anesthesia to measure the concentrations of gases such as anesthetic gas, oxygen (O2) and carbon dioxide (CO2) in an exhaled or inhaled breath. Either the mainstream or sidestream can be used for gas sampling.</td>
<td>37061000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracardiac oximeter module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement of the ratio of oxyhemoglobin to oxyhemoglobin consumed in the heart (SvO2: venous oxygen saturation) by comparing the absorptions of red light and infrared light of blood. The probe is inserted via a catheter (a Swan-Ganz catheter is often used).</td>
<td>37172000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicable</td>
<td>Notes</td>
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</tr>
<tr>
<td>Long-term recording electrocardiograph module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, used for the detection and recording of the patient's cardiac activity for 24 hours. Recording is performed while the patient is lying down (in the department of cardiology), and signals are stored on a cassette (magnetic tape), digital medium (with no movable parts) or other media, and subsequently analyzed by electrocardiographic equipment (ECG) and Holter equipment.</td>
<td>37175000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electromyographic module</td>
<td>A type of plug-in unit used for monitoring multiple items, and detecting and recording electromyogram signals (EMG signals). Measurement of electrical activity occurring in the muscle tissues may lead to diagnosis of muscular disorders.</td>
<td>37208000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Nerve location module</td>
<td>A type of plug-in unit usually used for monitoring multiple items and detecting the neural center in a certain body area. It consists of a neurostimulator and a receiver to record neural action potentials.</td>
<td>37246002</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroencephalographic module</td>
<td>A type of plug-in module intended for use with a multimodal-monitor, and used for the detection and recording of electroencephalogram (EEG) signals, produced as a result of electrical activity of the brain and detected by electrodes placed on the patient's forehead or scalp. Some types of device record auditory evoked potential (AEP) signals. The device is used for anesthesia, critical care, or other procedures.</td>
<td>37323000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Intracardiac oximeter</td>
<td>A device that measures the oxygen saturation of blood pumped from the heart to the lungs (SvO2-venous oxygen saturation). Measurement is performed by inserting a special catheter from a vein in the groin or neck. Catheters are not part of the device.</td>
<td>15200000</td>
<td>II</td>
<td>10-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Pulse oximeter</td>
<td>A device that perecutaneously measures oxygen saturation in blood (SpO2) by photodetection with a special probe. Light is generated within and irradiated from a light-emitting diode to pass through arterial blood, is received by the detector, and is measured by the principle of spectrophotometry. Some types of device have pulse rate, electrocardiogram (ECG), and capnogram computing capabilities.</td>
<td>17148010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Pulse oximeter/capnometer</td>
<td>A device used to monitor oxygen saturation (SpO2) and carbon dioxide (CO2). Parameters that can be monitored include end tidal carbon dioxide (EtCO2), fractional concentration of inspired carbon dioxide (FiCO2), arterial oxygen saturation (SpO2), pulse rate, and respiratory rate measurements.</td>
<td>17148020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment</td>
<td>A single device that has the ability to perform transcutaneous blood gas monitoring and pulse oximetry. (See the definitions of transcutaneous blood gas analyzer and of pulse oximeter.)</td>
<td>17148030</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment</td>
<td>A single sensor that can act as a transcutaneous blood gas sensor and pulse oximetry probe. (See the definitions of transcutaneous blood gas sensor and of pulse oximeter probe.)</td>
<td>17148040</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Neonatal monitor</td>
<td>A dedicated device that detects, processes and displays multiple vital sign parameters in newborns.</td>
<td>35569000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Fetal cardiac monitor</td>
<td>A device used for detecting, measuring and displaying fetal cardiac activity. Usually it measures fetal heart rate and also assesses heart valve movement. This device works non-invasively as follows: 1) It records fetal heart sounds electronically and graphically, 2) It discerns fetal electrocardiogram signals from maternal ones which are obtained from the maternal abdomen with the external electrode, 3) It sends and receives ultrasonic energy.</td>
<td>43958000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Uterine contraction monitor</strong></td>
<td>A device used for monitoring progress in labor (early uterine contraction). Through a transducer fixed on the abdomen of the woman during childbirth, this device measures the duration, frequency and relative pressure of uterine contractions. It usually has an alarm. Fetal parameters are not monitored.</td>
<td>17922000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cardiotocographic monitoring system</strong></td>
<td>A cardiotocograph (a device that records fetal heart rate and uterine contraction simultaneously). Usually, uterine contraction is measured by a tocometer, which is placed on the maternal abdomen. This device has a pressure transducer plate which lies...</td>
<td>37796000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Telemetry cardiotocograph system</strong></td>
<td>A set of systems for transmitting and receiving signals (usually electric signals) remotely, and for recording them. The system is intended for use in radio-telemetry for the continuous and ambulatory recording of fetal heart rate and uterine contractions.</td>
<td>38478000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Telemetry cardiotocograph receiver</strong></td>
<td>A part of the wireless telemeter system. It receives wireless signals from the transmitter that senses fetal heart rate and uterine contractions during labor.</td>
<td>38480000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Telemetry cardiotocograph transmitter</strong></td>
<td>A part of a wireless telemeter system. It transmits signals related to fetal heart rate and uterine contractions to the receiver.</td>
<td>38481000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Transcutaneous blood gas analyzer</strong></td>
<td>An automated or semi-automated device used to transcutaneously measure the oxygen (pO2) and carbon dioxide (pCO2) partial pressures in blood by using a special heating sensor which increases blood flow rate at the application site. The device is mainly used in...</td>
<td>36346000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Transcutaneous blood gas module</strong></td>
<td>A type of plug-in module usually intended for use with a multimodal-monitor, and used for the measurement of partial pressure of the gases (pO2, pCO2) in blood using a gas-sensitive membrane electrode and a heating sensor placed on the skin. Heating causes...</td>
<td>36889000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Transcutaneous blood gas sensor</strong></td>
<td>A device used to measure partial pressure of the gases (partial pressure of oxygen pO2) and carbon dioxide pCO2 in blood transcutaneously. Electric signals are transmitted to the base unit where signals are analyzed and results are usually displayed on the screen.</td>
<td>37178000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Subcutaneous blood gas analyser</strong></td>
<td>An automated or semi-automated device used to measure oxygen partial pressure (pO2) in the blood by inserting a special catheter, cannula or probe into the subcutaneous tissue. It has graph output and data output functions.</td>
<td>37199000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Airway pressure monitor</strong></td>
<td>A dedicated device used to measure and display the pressure values monitored at the upper respiratory tract in a patient (e.g., average maximal expiratory pressure and inspiratory static oral cavity pressure). The information obtained with this device is used for diagnosis. Usually, it incorporates a pressure indicator and a built-in alarm.</td>
<td>31318000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Gastrointestinal/esophageal motility monitor</strong></td>
<td>A system that monitors the gastrointestinal system and the esophagus to obtain data to be used for diagnosis. Usually, the system measures peristaltic movement, pressure, acidity, etc. in the stomach or the esophagus. Time series measurements of peristalsis and...</td>
<td>32081000</td>
<td>II</td>
<td>5-⑧,10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Fetal electroencephalographic monitor</strong></td>
<td>A device that detects, processes and displays electric signals occurring in the fetal brain. It shows the signals on an electroencephalogram (EEG).</td>
<td>32660000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hypopnea alarm</strong></td>
<td>A device used to diagnose insomnia accompanying hypopnea. The device records the phase difference between thoracic movement and abdominal movement to find slow and shallow respiration leading to decreased oxygen uptake. It gives alarm signals in the event the pre-specified limit is exceeded.</td>
<td>36974000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Num</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Telemetry electrocardiograph</td>
<td>A set of systems for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The system is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of electrocardiogram (ECO) signals. Functions of these devices include the telephonic transmission and recording function of ECG data.</td>
<td>31733000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electromyograph receiver</td>
<td>A part of a wireless telemeter system. This device receives wireless signals from the electromyogram (EMG) transmitter.</td>
<td>35556000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electroencephalograph</td>
<td>A set of systems for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The system is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of electroencephalogram (EEG) signals. Functions of these devices include the telephonic transmission and recording function of EEG data.</td>
<td>35626000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry pulse oximeter</td>
<td>A system that measures hemoglobin oxygen saturation and utilizes wireless communication in a part of the signal transmission pathway to eliminate hard-wired or other cable connections. This system is often employed to allow the patient to move freely.</td>
<td>36118000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electrocardiograph receiver</td>
<td>A part of a radio-telemetry system, intended to receive radio signals from an electrocardiogram (ECG) transmitter.</td>
<td>36365000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electroencephalograph transmitter</td>
<td>A part of a wireless telemeter system. This device transmits electroencephalogram (EEG) signals to the receiver.</td>
<td>36366000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electrocardiograph transmitter</td>
<td>A part of a radio-telemetry system, intended to transmit electrocardiogram (ECG) signals to a receiver.</td>
<td>36367000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electroencephalograph receiver</td>
<td>A part of a wireless telemeter system. This device receives wireless signals from the electroencephalogram (EEG) transmitter.</td>
<td>36381000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry pulse oximeter transmitter</td>
<td>A part of a radio-telemetry system, intended to transmit arterial oxygen saturation (SpO2) signals.</td>
<td>37353000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electromyograph</td>
<td>A set of systems to transmit and receive signals (usually electric signals) remotely, and to record them. The system is intended for use particularly in radio-telemetry for continuous and ambulatory recording of electromyogram (EMG) signals. Functions for telephonic applications.</td>
<td>37794000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry electromyograph transmitter</td>
<td>A part of a wireless telemeter system. It transmits electromyogram (EMG) signals to the receiver.</td>
<td>38443000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Product Description</td>
<td>Function</td>
<td>Class</td>
<td>Level of Evidence</td>
<td>Appropriateness</td>
<td>Appropriateness</td>
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</tr>
<tr>
<td>Telemetry pulse oximeter receiver</td>
<td>A part of a radio-telemetry system, intended to receive radio signals from a pulse oximetry transmitter.</td>
<td>38557000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry physiological signal system</td>
<td>A set of system for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The device is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of biological signals except electrocardiograms (ECG), electroencephalograms (EEG), electromyograms (EMG), and fetal signals.</td>
<td>32547000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry ECG receiver module</td>
<td>Usually, a type of plug-in unit used for a multiparameter monitor and to receive (wireless) ECG signals transmitted through the air via the patient’s receiver (remotely). When it is used by a patient walking in the hospital or ward within the area the receiver is used.</td>
<td>37176000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Telemetry data transmitter</td>
<td>A part of a radio-telemetry system, intended to transmit data measured by an instrument (e.g., standalone multigas analyzer) to the central monitor.</td>
<td>37206000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term respiration pulmonary function data recorder</td>
<td>A device that records lung function (e.g., respiratory rate) as the carrying information for diagnosis over a long period (usually for 24 hours or longer). It is attached to a patient’s body and carried by the patient. The recorded measured values (data) are downloaded to an appropriate analysis system in the hospital for analysis.</td>
<td>16305000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term body temperature data recorder</td>
<td>A device that records temperature as the trend information for diagnosis over a long period (usually for 24 hours or longer). It is attached to a patient’s body and may be carried by the patient. The recorded measured values (data) are used as the appropriate information in the hospital.</td>
<td>17572000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Pneumographic data recorder</td>
<td>A device that graphically displays chest movement during respiration. Utilizing a sensor (e.g., electrical impedance), the device detects and transduces chest movement during respiration. Both the speed and waveform of the movement may be displayed.</td>
<td>35244000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Pneumotachographic data recorder</td>
<td>A device that graphically records the air volume per one respiration during inspiration or expiration based on the momentary air flow (velocity) in the oral cavity and consolidated data.</td>
<td>35245000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Nerve function monitor</td>
<td>A device used to monitor the function of individual nerves or nerve bundles. The functional integrity of nerves may change during surgery due to trauma, anesthesia, or other factors; therefore, it is important to know whether any change has occurred, and the timing of the occurrence.</td>
<td>36081000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term physical activity data recorder</td>
<td>An automatic device that measures and records patient movement over a long period (usually for 24 hours or longer). It is carried by the patient and performs daily activities. Physical activities are detected by a transducer and signals are transmitted to the counting and timer circuits. Activities are recorded for several days.</td>
<td>36252000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term urodynamic data recorder</td>
<td>A device that records urinary dynamics for 24 hours. It is carried by the patient. Data obtained are analyzed in the hospital.</td>
<td>36964000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Esophageal catheter with pH sensor</td>
<td>A catheter with a pH sensor at the tip. It is mainly used to determine the pH in the stomach and the esophagus.</td>
<td>70077000</td>
<td>II</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Icterometer</td>
<td>A device used to noninvasively measure serum bilirubin concentrations by the absorption spectrophotometry method in which absorption of light irradiation by bilirubin deposited</td>
<td>70078000</td>
<td>II</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Pediatric pulmonary function analyser</td>
<td>A device used to measure and record neonatal or pediatric respiratory function (usually based on tidal volume, ventilation frequency, minute ventilation, airway compliance, airway resistance).</td>
<td>36134000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Peak flow spirometer</td>
<td>A device used to measure the maximal ventilation flow rate (maximal expiratory volume per unit time) for comparison with the normal value or previous value. The device helps to detect diseases including asthma, emphysema and bronchitis. It is usually called a peak flow meter.</td>
<td>31300000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Respiratory flow meter</td>
<td>A device that determines the expiratory flow rate based on airflow velocity measured with a respiratory transducer.</td>
<td>70079010</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Type</td>
<td>Status</td>
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</tr>
<tr>
<td>Respiratory resistance meter</td>
<td>A device that measures respiratory resistance based on the external air pressure and respiratory flow rate as measured by the respiratory transducer.</td>
<td>70079020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered diagnostic spirometer</td>
<td>An electric device used to measure the air volume and airflow velocity in the lungs, for diagnosis or investigation of lung diseases. The measurements provide information about the patient's lung function, allowing comparison with a normal value or previously measured data.</td>
<td>13680002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Oxyhemoglobin analyzer</td>
<td>An automated or semi-automated device that measures the concentration of hemoglobin bound to oxygen in the blood.</td>
<td>33275000</td>
<td>II</td>
<td>10⁻¹</td>
<td>applicable</td>
</tr>
<tr>
<td>Functional oximeter</td>
<td>A device used to measure the changes in the hemoglobin concentration in the blood by detecting infrared light irradiated to the body.</td>
<td>70080000</td>
<td>II</td>
<td>10⁻¹</td>
<td>applicable</td>
</tr>
<tr>
<td>Basal metabolism measuring system</td>
<td>A device to determine basal metabolism. It may be used with a ventilator.</td>
<td>70081000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Nitrogen gas analyzer</td>
<td>A device that measures the concentration of nitrogen in expired or inspired air using an electrochemical method, mass spectrum method, ultraviolet absorption method, or infrared absorption method.</td>
<td>31338000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Carbon dioxide gas analyser</td>
<td>A device designed to measure the concentration of carbon dioxide in a mixed gas by the electrochemical method, infrared absorption, gas chromatography, or mass spectrometry to assess ventilation, circulation, and metabolic conditions.</td>
<td>31339000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Hydrogen gas analyzer</td>
<td>Usually, a device to measure the exhaled hydrogen (H2) concentration.</td>
<td>37252000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Nitrogen dioxide gas analyzer</td>
<td>A device that measures the concentration of nitrogen dioxide (NO2) in expired or inspired air using an electrochemical method, mass spectrum method, ultraviolet absorption method, or infrared absorption method.</td>
<td>37269000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Capnometer</td>
<td>A device intended to monitor carbon dioxide.</td>
<td>17148050</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Carbon dioxide carbon isotope ratio analyzer</td>
<td>A device that measures changes in the carbon dioxide (CO2) concentration in mixed gas, the carbon isotope ratio (13C/12C) in exhaled carbon dioxide, or others using an electrochemical method, infrared absorption method, gas chromatography method, or mass spectrometry to determine ventilation, circulatory and metabolic conditions.</td>
<td>70082000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
</tbody>
</table>
| Medical Device Description                                                                 | Description                                                                                                                                                                                                 | Code   | Class | Valuation | Availability
|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------|-----------|-------------
| Adult pulmonary function analyzer                                                      | A device used to measure pulmonary function and efficiency (usually, ventilation, diffusion, and distribution of a gas in the lungs) in adult patients.                                                      | 35282010 | II    | 10        | applicable
| Respiratory function measuring system                                                   | A device intended to measure gas exchange (ventilation, diffusion, and distribution), respiratory center function, respiratory muscle function, and other lung function as well as pulmonary efficiency and the condition of the bronchi. | 35282020 | II    | 10        | applicable
| Nasal resistance unit                                                                    | A device used for the measurement of the air flow and pressure change in the nasal cavity in order to determine the state of the nasal cavity. The device is used to determine the degree of nasal obstruction or nasal congestion. These devices may be simple manometer. | 17228000 | II    | 10        | applicable
| Water vapour gas analyzer                                                                | A dedicated device to measure the water vapor level in the air expired from the lungs using mass spectrometry.                                                                                              | 31271000 | II    | 10        | applicable
| Differential gas pressure transducer                                                    | A medical 2-chamber device often used for pulmonary function tests. Electric signals are generated in proportion to the difference in gas pressure between the 2 chambers. Next, measured values are processed and displayed with the base unit. | 31293000 | II    | 10        | applicable
| Long-term monitoring spirometer                                                         | A device that continuously measures the tidal volume and minute volume rates in a patient to assess the ventilation function. An alarm system for the high tidal volume and low tidal volume may be installed in the device. | 35353000 | II    | 10        | applicable
| Carbon monoxide gas analyzer                                                            | A device that measures the carbon monoxide concentration in mixed gas to be used as a reference for assessment of metabolic and respiratory conditions. Techniques including electrochemical analysis, infrared absorption, gas chromatography, or mass spectrometry. | 35467000 | II    | 10        | applicable
| Pulmonary exercise stress monitoring system                                             | A device for exercise test that measures respiratory gases by using oxygen (O2) and carbon dioxide (CO2) analyzers, in addition to other pulmonary function parameters during exercise. The device measures and calculates the patient's respiratory parameters with a mask mouthpiece or hood attached to a tube that connects the patient and the gas. | 36146000 | II    | 10        | applicable
| Diagnostic positive airway pressure unit                                                 | A unit used to examine a patient suspected of having sleep apnea and its complications. By analyzing the recorded data, the patient's condition can be assessed, and the appropriate medication can be prescribed. | 37235000 | II    | 10        | applicable
| Nitric oxide gas analyzer                                                                | A device to measure and assay the nitrogen oxide (NO) concentration in mixed gas. This device is used to measure the NO concentrations in expired and inspired air during special respiratory treatment. NO gas is effective only when a very small amount of the gas is used. Therefore, the data obtained with this device is important. | 37268000 | II    | 10        | applicable
| X-ray computed tomography system xenon gas administration system                        | A component of an X-ray computed tomography system. The xenon gas delivery device used for diagnostic radiography systems is designed to supply xenon gas (via inhalation or injection) when a real-time imaging examination of physical or physiological parameters, such as blood flow, is performed. | 40907000 | II    | 11        | applicable
| Nuclear medicine xenon gas administration system                                        | A component of a nuclear medicine imaging device such as a gamma camera or SPECT. A xenon gas re-breathing device is used to deliver xenon gas to the patient or to collect the radioactive xenon gas in expired gas in a real-time imaging examination of physical or physiological parameters such as pulmonary function or blood flow. The device is designed to reduce the emission of radioactive gases into the atmosphere during imaging. | 40908000 | II    | 11        | applicable
| Single-use nuclear medicine xenon gas inhalation set                                     | A device used to deliver xenon gas to the patient, and to collect radioactive xenon in expired gas following an imaging examination of physical or physiological parameters, such as pulmonary function or blood flow. The device is designed to suppress emission of radioactive gases into the atmosphere. | 70084000 | II    | 11        | N/A
<table>
<thead>
<tr>
<th>Device Type</th>
<th>Description</th>
<th>Code</th>
<th>Class</th>
<th>Ref</th>
<th>Applicable</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-gas monitor</td>
<td>A multi-gas monitor intended to monitor the concentrations of oxygen, carbon dioxide, nitrous oxide, or anesthetic gas in expired or inspired air of the patient, and respiratory rate or other parameters.</td>
<td>70085000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pulmonary function testing filter</td>
<td>A device used to remove saliva, sputum, and other contaminating microdroplets produced by the patient during pulmonary function tests. The device is intended for single-use.</td>
<td>70086000</td>
<td>II</td>
<td>3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Respiratory circulation testing equipment</td>
<td>A testing device that can perform at least 2 types of tests out of a respiratory function test, a basal metabolism test and a pulmonary exercise test.</td>
<td>70088000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Automatic perimeter/ophthalmic camera</td>
<td>A multifunctional device that functions as an ophthalmic camera and performs automated perimetry.</td>
<td>16918002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Refractokeratometer/tonometer</td>
<td>A multifunctional device with the capabilities of tonometer and refractor/keratometer.</td>
<td>36387060</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic interferometer</td>
<td>A device to determine the retinal visual acuity with interference fringes. For example, the device is sometimes used to measure light wavelength during eye surgery. The device is often used for cataract surgery.</td>
<td>36397000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Aqueous/flare cell analyzer</td>
<td>A device that measures anterior chamber flare (protein content) and the number of cells in the aqueous humor.</td>
<td>37948000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Eye movement testing equipment</td>
<td>A device that measures eye movement by processing images of the eye captured by the camera. Some types of device have a built-in angular velocity sensor, with the ability to analyze the data.</td>
<td>70093000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Optical intraocular measuring instrument</td>
<td>A device that optically measures dimensions of components of the eye such as corneal radius of curvature, corneal thickness, anterior chamber depth, and axial length.</td>
<td>70096000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Level</td>
<td>Applicable Status</td>
<td>Notes</td>
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<tr>
<td>Temograph</td>
<td>A device to record involuntary shaking or tremulousness (tremor). This has a built-in sensor that senses movements of the finger, hand and arm in various resting positions. The movements are directly recorded with a recording pen or electrical transducer (in a highly sensitive recording).</td>
<td>14144000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Neuropathological diagnostic quantitative sensory tester</td>
<td>A device used to test and determine the level of vibration required to measure the vibration perception threshold of a certain area of the skin. The device is used for the diagnosis of neuropathological conditions, and to detect conditions, such as suspected diabetes, exposure to neurotoxic substances (e.g., solvents and heavy metals), poor working conditions, and early symptoms of disorders caused by traffic accidents or other events.</td>
<td>37349000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Noise generating audiometer</td>
<td>A device consisting of an electronic generator, amplifier, and earphone. The device is used to make masking noise for the non-tested ear during an audiometric test. The device is used to minimize the non-test ear's perception of the test sound, which is generated at the test ear.</td>
<td>31939000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Visual reinforcement audiometer</td>
<td>An electroacoustic device intended for use in audiometric tests on infants. With appropriate responses to test signals, pictures attractive to infants are displayed as a reward.</td>
<td>34013000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Pure-tone audiometer</td>
<td>An audiometer capable of both air conduction and bone conduction measurements. Usually, the device is equipped with earphones and a headband, which provide a pure tone of specified frequency at known sound pressure levels to one ear at a time. Some devices are equipped with a bone conduction vibrator. For clinical use, in addition to the both capabilities, a function of generating calibrated masking noise is necessary. The device is typically used with speech audiometry capability excluded.</td>
<td>37503000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Manually-operated audiometer</td>
<td>An electroacoustic device that manually presents signals, allows selection of frequency and hearing level, and records the subject's response. Devices with speech audiometry capability are excluded.</td>
<td>41184000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Automatic-recording audiometer</td>
<td>An electroacoustic device that automatically presents signals, selects or modifies frequency, modifies hearing level, and records the subject's response. Change in the hearing level is controlled by the patient. The devices may have the ability to generate a fixed frequency, or a continuously changing sweep frequency. Some devices generate both continuous and pulsed test tones. Devices with speech audiometry capability are excluded.</td>
<td>41185000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Computer-controlled audiometer</td>
<td>An electroacoustic device in which test procedures are controlled by a computer or microprocessor. Unlike an automatic recording audiometer, test signal levels are not controlled by the patient. Usually, calculation of hearing levels according to the patient's response and displaying are also performed. Devices with speech audiometry capability are excluded.</td>
<td>41187000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Speech audiometer</td>
<td>An electroacoustic device for audiometry using speech testing materials. Pure tone audiometers are often equipped with the capability to be used as speech testing audiometers, by connecting a device that supplies pre-recorded speech material via the external input port.</td>
<td>41188000</td>
<td>II</td>
<td>10-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Impedance audiometer</strong></td>
<td>An electroacoustic device that evaluates the acoustic impedance/admittance of the human ear by means of acoustic probe signals. The practical use of this device involves measuring the changes in acoustic impedance/admittance caused either by varying the air pressure in the external acoustic meatus or by activating the middle ear muscle reflex. The results are used to diagnose various hearing disorders.</td>
<td>36717010</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Impedance audiometer with pure-tone and speech audiometric functions</strong></td>
<td>An electroacoustic device that evaluates the acoustic impedance/admittance of the human ear by means of acoustic probe signals. The device has both pure-tone threshold audiometry and speech audiometry capabilities.</td>
<td>36717020</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Objective audiometry device</strong></td>
<td>A device used in audiometry to detect and record local potentials generated in the brain or spinal cord in response to stimuli (e.g., visual, acoustic, and somatic sensation) applied to a sense organ or at a point in the afferent tract of a sense organ, or in the central nervous system. The characteristics of recorded electrical potentials differ depending on the recording site, form and amount of stimulation evoked, level of consciousness, and anesthetic levels. Obtained waveforms may be used for the evaluation of the function and integrity of the brain and its sensory system.</td>
<td>11614000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Otoacoustic emission instrument</strong></td>
<td>A device used to record and analyze weak sounds coming from the ear. Types of stimuli that generate such sounds include spontaneous otoacoustic emission, a click stimulus (otoacoustic emission evoked by transient stimuli), or a tone-burst stimulus (distortion product otoacoustic emission).</td>
<td>36908000</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Eustachian tube function testing instrument</strong></td>
<td>A device intended for the diagnosis of conditions such as patulous Eustachian tube or stenosis of the Eustachian tube, used to observe or record the changes in the characteristics of sound passing between the nasal cavity and external acoustic meatus associated with swallowing movements, and the process of releasing pressure in the middle ear cavity by swallowing.</td>
<td>70097000</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Auditory evoked response audiometer with otoacoustic emission measurement function</strong></td>
<td>An electronic acoustic device used to evaluate the activity of the auditory nervous system with the response to an acoustic signal at the ear. The response is detected via a scalp electrode. The device also has the ability to record and analyze weak sounds from the ear. Types of stimuli that generate sounds include spontaneous otoacoustic emission, a click stimulus.</td>
<td>35747020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Rotational/pendular/linear motions stimulator</strong></td>
<td>An electric motor-driven chair that provides quantitatively reproducible, acceleratory stimulation to the otolith organ of the inner ear. This chair can perform rotary movement, pendular movement or linear movement.</td>
<td>70098000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Biomechanic platform system</strong></td>
<td>A system that uses a tilting balance platform consisting of a sensor, computer and special software to test the balance of a patient. The patient controls the center of gravity (tilting in one direction) following the instructions of the physician or according to the instability.</td>
<td>17242002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Quantitative sensory test odorimeter</strong></td>
<td>A device used to assess the sense of smell in a patient quantitatively and qualitatively. There are a variety of components to the device, such as a rack of vials with various types of odor, and a sliding device for test tubes. Usually, the device is used for patients with head injuries which may change the sense of smell.</td>
<td>12796000</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Tonoscope</strong></td>
<td>A device used to visualize sounds by recording vibrations on the screen. This is used to examine the head or the brain using sounds.</td>
<td>14069000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>applicable</td>
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<tr>
<td>Vestibular function caloric stimulator</td>
<td>A type of stimulator that applies a stream of air or water as a thermal stimulus to the external acoustic meatus. A vestibular function stimulator consisting of a perfusion system that includes a pump, valves, heaters, and regulators to control the flow rate and temperature of the medium. Stimulation of the semicircular canal induces involuntary eye movements, which can be measured using a nystagmograph. These stimulators are used for vestibular function testing in evaluating the patient's balance system.</td>
<td>34891000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Touch discrimination quantitative sensory tester</td>
<td>A device used to examine the area of the skin with normal, increased or reduced sensitivity, and to determine the threshold of the sense of touch during a neurological examination. The examination is performed by means of various methods as follows: 1.</td>
<td>35056000</td>
<td>II</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Electromagnetic stimulator</td>
<td>A type of stimulator that delivers electromagnetic energy to tissues at the levels below the heat sensation threshold. Usually, the device increases the temperature of the target tissue by less than 1ºC utilizing high-frequency energy with a short pulse.</td>
<td>35169000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
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</tr>
<tr>
<td>Nerve locator stimulator</td>
<td>A device used to locate a nerve intermittently, in order to monitor the positional relationship between the nerve and surgical instruments (e.g., scalpel). The device consists of a nerve stimulator and a receiver that records nerve signal activity.</td>
<td>35723002</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
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</tr>
<tr>
<td>Local anesthesia nerve stimulator</td>
<td>A battery powered nerve stimulator used to locate an appropriate nerve in a particular area of the body before a local anesthetic is administered. By stimulating the area with electric current, a muscle reflex is activated and can be monitored. Muscle reflexes can be measured.</td>
<td>37042000</td>
<td>II</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Quantitative sensory test thermal analysis system</td>
<td>A device that quantitatively assesses and diagnoses responses to heat stimulation (usually, responses on the skin surface) in order to obtain information about the hot-cold sensation threshold. The device can be either invasive or non-invasive. The device is used for detection of early diabetes mellitus or a phantom pain, diagnostic tests including neurological examination related to nerve fibers, and a pain threshold test. These examinations are performed with the skin temperature raised to approximately 42ºC to 50ºC.</td>
<td>37350000</td>
<td>II</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Temperature discrimination quantitative sensory tester</td>
<td>A quick testing device used to determine the area where thermal perception is impaired. Tests are performed by applying a charged roller heated to pre-specified temperatures, e.g., 25ºC and 49ºC (normal skin temperature is 30ºC to 32ºC). The patient distinguishes corresponding sensations, and sites with normal and abnormal sensation are mapped.</td>
<td>38826000</td>
<td>II</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Single-use nerve locator</td>
<td>A single-use nerve locator used for distinguishing or locating a motor nerve, or for electromyography during surgery. The device consists of a needle electrode, which will be inserted subcutaneously, a probe electrode which will be in contact with skin tissue, and an electromyography device.</td>
<td>70099000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Electrogustometer</td>
<td>A device used to test the sense of taste. Electrical stimuli are applied by allowing the electrode to contact the tongue, and the electric current threshold of taste perception is measured.</td>
<td>70100000</td>
<td>II</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Optokinetic stimulator</td>
<td>A device used to stimulate the nerves associated with equilibrium such as the vestibular nerve with visual stimuli, to evoke eye movements by the vestibulo-ocular reflex, in order to measure the degree of equilibrium disturbance.</td>
<td>70201000</td>
<td>II</td>
<td>10</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Powered cutaneous pain gauge</td>
<td>An electric device used to determine sensitivity to pain (such as a sharp pin prick). The device is also called an algosimeter.</td>
<td>12950002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Physiologic neuromuscular function analyzer</td>
<td>A device used to determine and assess physical or joint movement for the purpose of graphic display of the body and bionics analysis such as spine analysis or joint movement testing. The device can be also used to determine the severity of ataxia (disturbance of muscle coordination). It is usually used for testing mechanisms/tasks related to sport, work and rehabilitation. The device may contain a variety components including a unit utilizing optoelectronics or electricity and magnetism, a marker, a sensor, a video camera, an image processor, and a computer.</td>
<td>17929000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td></td>
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<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
<td>Status</td>
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<tr>
<td>Myograph</td>
<td>A device that determines and records various phases of muscle contraction including strength or velocity. It has a built-in sensor to detect and graphically reproduce displacement or power related to muscle contraction (myogram). The device is used to assess the muscle under some conditions including displacement under continuous tension and the power produced under isometric conditions.</td>
<td>12692000</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Perineometer</td>
<td>A device consisting of a bag connected to an external pressure gauge. The bag contains liquid to be injected into the vagina. The device determines perineal muscle strength through resistance to spontaneous contraction of the perineal muscle. The device is used to diagnose and treat urinary incontinence and sexual dysfunction through movement.</td>
<td>32686000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Spine curvature monitor</td>
<td>A device that detects, displays, and records the position of several vertebrae adjacent to each other.</td>
<td>34037000</td>
<td>II</td>
<td>10-1</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Quantitative sensory test palpometer</td>
<td>A device that inspects and determines the threshold of pain perception in patients suspected of having disorders. Some types of device utilize multiple measurement techniques. The device usually detects the initial phase of the reflex escape response, which is called the pressure pain threshold.</td>
<td>40817000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Cruciate ligament function testing equipment</td>
<td>A device used to evaluate cruciate ligament function.</td>
<td>70102000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Fundus camera</td>
<td>A device used to take images of the ocular fundus (inside the eyeball, the posterior fundus) through the pupil.</td>
<td>10551000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic camera</td>
<td>A camera specifically designed to record still images of the eye and ocular fundus (when fluorescein angiography technique is used, angiographic images). In some devices, light may be illuminated from the objective lens, and take retinal images (at 1 second intervals) by adjusting the position with the eye, or may document pathology of the ocular fundus and provide diagnostic data.</td>
<td>16419000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Laryngostroboscope unit</td>
<td>A device used to observe phonation within the pharynx. The device is usually used in conjunction with other devices constituting the system, and an appropriate laryngoscope. The device is used for the testing of phonation (glottic) function, and assessment of dysphonia.</td>
<td>31923000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Fat/lean analyzer</td>
<td>A device used to measure body fat and fat-free mass. The measurement results are shown by weight.</td>
<td>36022010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Body composition analyzer</td>
<td>A device used to measure body water content (intra- and extracellular fluid volume), lean body mass and other parameters by using bioelectrical impedance analysis (BIA).</td>
<td>36022020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Phonatory function testing equipment</td>
<td>A device that monitors and records the strength of phonation, fundamental frequency, expiratory flow, and other physical quantities, used for the diagnosis of dysfunction of the vocal organs. Some devices include the ability to calculate the correlation between these physical quantities and their stability.</td>
<td>70103000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Instrument Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Year</td>
<td>Applicable</td>
<td>Remarks</td>
</tr>
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<td>---------------------------------------------------------------------------------------</td>
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<tr>
<td>Tongue pressure measuring instrument</td>
<td>A device to determine lingual pressure electrically.</td>
<td>70104000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Endoscopic telescope</td>
<td>One of the components of an endoscopic system that consists of a variety of components to function. The device consists of a rigid or flexible endoscope with an image transmission system based on a relay lens, optical fiber, or solid-state image sensing device. It is usually connected to a fiber cable to provide light from the light source. The device may be inserted through a sheath. The device is used to examine a body cavity or organ via a natural or an artificial opening.</td>
<td>37084000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible duodenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the duodenum (upper gastrointestinal tract up to the proximal duodenum). The device is intended to examine the mucous membranes, gallbladder, pancreas, stomach and other organs. A fiber optic bundle is used for image transmission.</td>
<td>35020000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible gastroduodenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of that part of the gastrointestinal tract that extends from the stomach to the duodenum. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. A fiber optic bundle is used for the image transmission system.</td>
<td>35087000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Gastroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the stomach. It is inserted through the mouth, or an artificial opening. The insertion section is flexible, and a fiber optic bundle is used for image transmission.</td>
<td>35088000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible esophagoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section changes its shape corresponding to the shape of the body cavity. The device is inserted through the oral cavity. The image transmission system comprises a fiber optic bundle.</td>
<td>36631000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible sigmoidoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. It is a fiberscope in which the insertion section is flexible allowing modification of the shape depending on the shape of the cavity; a fiber optic bundle is used for image transmission.</td>
<td>15057000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible colonoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the colon. The insertion section is flexible, and is inserted through the anus. A fiber optic bundle is used for image transmission.</td>
<td>34966000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible pancreatoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the pancreas. A fiber optic bundle is used for image transmission, and the insertion section is flexible. The device is usually inserted into the working channel of a duodenoscope, and is inserted through the papilla of Vater.</td>
<td>32253000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible choledochoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the biliary tract. The insertion section is flexible, is inserted through the incised part of the abdomen, and can also be inserted through a flexible duodenoscope. The device is a fiberscope in which a fiber optic bundle is used for image transmission.</td>
<td>34898000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible nasopharyngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. The image transmission system comprises a fiber optic bundle.</td>
<td>35204000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Category</td>
<td>Specializations</td>
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<tr>
<td>Flexible bronchoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is flexible. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>35461000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible nephroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the kidney. The device is percutaneously inserted into the renal pelvis. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>35502000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible cystoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper urinary tract). The insertion section is flexible, and changes the shape corresponding to the shape of the cavity. The device is a fiberscope.</td>
<td>35980000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible enteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the small intestine. The device is used during surgery of the small intestine. The device may be of push type (introduced by guidance under direct vision) or probe type (having an inflatable.</td>
<td>36298000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible culdoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device is a flexible endoscope, and a fiber optic bundle is used for image transmission.</td>
<td>36624000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible cystourethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder and the urethra (including the prostate area) in male patients. The insertion section is flexible. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>36632000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible thoracoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a flexible endoscope, and a fiber optic bundle is used for image transmission.</td>
<td>36639000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible ureteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder), and renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>36640000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible laryngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the larynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>36645000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible intubation laryngoscope</td>
<td>An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity.</td>
<td>36706010</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible pharyngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>36709000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible ureterorenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The image transmission system comprises a fiber optic bundle.</td>
<td>37111000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible hysteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a flexible endoscope which changes its shape corresponding to the shape of the body cavity.</td>
<td>37152000</td>
<td>II</td>
<td>5-①</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible laparoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. It is inserted through an artificial opening on the abdominal wall (usually, immediately below the navel). The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.</td>
<td>70106000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
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</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Classification</td>
<td>Applicability</td>
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</tr>
<tr>
<td>Flexible stomatoscope</td>
<td>An endoscope used for visual examination of the oral cavity. The insertion section is flexible, and comprises an optical system such as an image fiber.</td>
<td>70107000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible antroscope</td>
<td>An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. This device is a flexible endoscope.</td>
<td>70109000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible lacrimal passage endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is flexible with a fiber optic bundle.</td>
<td>70110000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible mammary ductoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is flexible with a fiber optic bundle.</td>
<td>70111000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible plastic surgery endoscope</td>
<td>An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is flexible with a fiber optic bundle.</td>
<td>70112000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible ear endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. This device is a flexible endoscope.</td>
<td>70114000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible salpingoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. A fiber optic bundle is used in the image transmission system.</td>
<td>70115000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible arthroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is flexible, and has a fiber optic bundle.</td>
<td>70116000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible mediastinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is flexible, and has an optical fiber tube bundle as an image transmission system.</td>
<td>70117000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible urethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary tract. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a fibrescope with a fiber optic bundle for image transmission.</td>
<td>70118000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Instrument Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Approval</td>
<td>Available</td>
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</tr>
<tr>
<td>Flexible rhinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a flexible endoscope, and has a fiber optic bundle.</td>
<td>70119000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible sinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a flexible endoscope, and has an optic fiber imaging system.</td>
<td>70120000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible rhino-laryngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a fiberscope with a fiber optic bundle for image transmission.</td>
<td>70121000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video bronchoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is flexible, and changes the shape corresponding to the shape of the cavity. A solid state image sensing device is used for the image transmission system.</td>
<td>17662000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video gastroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the stomach. The device is inserted through the oral cavity or an artificial opening on the stomach wall. A solid-state image sensing device is used for the image transmission system. The insertion section is usually flexible.</td>
<td>17663000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video sigmoidoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. The device is a videoscope in which the insertion section is flexible and changes its shape corresponding to the shape of the body cavity; a solid-state image sensing device is used for image transmission.</td>
<td>17664000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video cystourethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder, and the ureter (including the prostate area) in male patients. The insertion section is flexible. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>32019000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video laryngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the larynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>35462000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Endoscopic video imaging system</td>
<td>A system that displays a video image transmitted from the videoscope to the display screen. The operator and assistant can observe the treated site with this system. It usually consists of a videoscope, an endoscopic camera, a camera control unit, a light source and light source cable, a video recorder, an image processor (sometimes with color calibration), a visual display unit (e.g., television monitor manufactured for medical devices).</td>
<td>35616000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video duodenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the duodenum (upper gastrointestinal tract up to the proximal duodenum). The device is intended to examine the mucous membranes, gallbladder, pancreas, stomach and other organs. A solid-state image sensing device is used for the image transmission system.</td>
<td>36112000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Endoscope Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Intended Use</td>
<td>Compatibility</td>
<td></td>
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</tr>
<tr>
<td>Flexible video colonoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the colon. The insertion section is flexible, and is inserted through the anus. A solid-state image sensing device is used for the image transmission system.</td>
<td>36117000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video laparoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually immediately below the navel). A solid-state image sensing device is used for image transmission.</td>
<td>36283000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid video laparoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually immediately below the navel). The insertion section is either rigid or flexible. The device is inserted through an artificial opening in the abdominal wall.</td>
<td>43053000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video enteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the small intestine. The device is used during surgery of the small intestine. The device may be of a push type (introduced by guidance under direct vision) or probe type (having an inflatable tip). The insertion section is flexible, and is inserted through the oral cavity.</td>
<td>36299000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video choledochoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the biliary tract. The insertion section is flexible, is inserted through the incised part of the abdomen, and can also be inserted through a flexible duodenoscope. A solid-state image sensing device is used for image transmission.</td>
<td>36626000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video nephroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the kidney. The device is percutaneously inserted into the renal pelvis. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>38663000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video esophagoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is inserted through the oral cavity. This is a video device in which a solid-state image sensor is used for image transmission.</td>
<td>38666000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video ureteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder), and renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>38689000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video pharyngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>38691000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video ureterorenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>38703000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video gastroduodenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of that part of the gastrointestinal tract that extends from the stomach to the duodenum. The device is flexible, which changes its shape depending on the shape of the body cavity.</td>
<td>38805000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video intubation laryngoscope</td>
<td>An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity.</td>
<td>70123010</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid video intubation laryngoscope</td>
<td>An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. In some devices, the insertion section is rigid, and the tip is rigid.</td>
<td>70123020</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Flexible video stomatoscope</td>
<td>An endoscope used for visual examination of the oral cavity. The insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70124000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
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</tr>
<tr>
<td>Flexible video antroscope</td>
<td>An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. The device is a flexible videoscope.</td>
<td>70126000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video lacrimal passage endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70127000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video mammary ductoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70128000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video plastic surgery endoscope</td>
<td>An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70129000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video ear endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. The device is a flexible videoscope.</td>
<td>70131000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video salpingoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70132000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video arthroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70133000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video mediastinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is flexible, and uses a solid-state image sensing device.</td>
<td>70134000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video urethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary tract. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70135000</td>
<td>II</td>
<td>5-○</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video rhino-laryngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70136000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video rhinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a videoscope with a solid-state image sensing device.</td>
<td>70137000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video sinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a videoscope with a solid-state image sensing device.</td>
<td>70138000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video thoracoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a flexible videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70139000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video hysteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a flexible endoscope which changes its shape corresponding to the shape of the body cavity or the lumen of a device. A solid-state image sensing device is used for image transmission.</td>
<td>70141000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video pancreatoscope</td>
<td>An endoscope used for visual examination and diagnosis of the pancreas. The device is usually connected to the working channel of a duodenoscope, and is inserted through the papilla of Vater. The insertion section is flexible, and uses a solid-state image sensing device for image transmission.</td>
<td>70143000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video nasopharyngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a flexible endoscope that changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70145000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video cystoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper ureter). The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70146000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flexible video culdoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device consists of a flexible endoscope and a videoscope in which a solid-state image sensing device is used for image transmission.</td>
<td>70147000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid nephroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the kidney, renal pelvis, major calyces, and minor calyces. The device is percutaneously inserted into the renal pelvis. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity or through the outer cylinder of the device. Relay lens optics are used for image transmission.</td>
<td>15290000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid cystoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper urinary tract). The insertion section is rigid. Relay lens optics are used for image transmission.</td>
<td>17145000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
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</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Code</td>
<td>5</td>
<td>Applicability</td>
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<tr>
<td>Pyeloscopy kit</td>
<td>A kit of packaged tools including devices, instruments, and other accessories necessary for pyeloscopic procedures. An endoscopic device necessary for the pyeloscopic procedures may be included. The kit is considered to be reusable even if some of the accessories need repair.</td>
<td>32083000</td>
<td>II</td>
<td>6.9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid resectoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment, especially for resection of tissues (e.g., enlarged prostate gland or endometrium). The device usually consists of a rigid outer cylinder, optical telescope, working element, and a scalpel for incision.</td>
<td>35301000</td>
<td>II</td>
<td>5.0</td>
<td>9 applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid urethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urethra including the prostate area in male patients. The insertion section is rigid.</td>
<td>35423000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid cystourethroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder and the urethra. The insertion section is rigid.</td>
<td>36652000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid ureteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder) and renal pelvis through the external urethral orifice. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission.</td>
<td>36654000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid ureterorenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. Some types use a fiber optic bundle for image transmission.</td>
<td>37112000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid urethrotome</td>
<td>An endoscope used for visual examination, diagnosis, and treatment, especially for incision, of a narrowed part of the urethra. The device usually consists of a rigid outer cylinder, optical telescope, working element, and a scalpel for incision.</td>
<td>17633000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid anoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the anal canal and lower rectum. The device is a rigid endoscope, and has relay lens optics for image transmission.</td>
<td>10156002</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid gastroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the stomach. The device is inserted through the oral cavity or an artificial opening on the stomach wall. The device is a rigid endoscope. A relay lens optics system is used for image transmission.</td>
<td>11858000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid laparoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually, immediately below the navel). The device is a rigid endoscope, and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. Relay lens optics are used for image transmission. Some types use a fiber optic bundle for image transmission, and the tip may be bent.</td>
<td>12291000</td>
<td>II</td>
<td>6.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid sigmoidoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission.</td>
<td>15058000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid bronchoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is rigid, and relay lens optics are used for image transmission.</td>
<td>15074000</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid intubation laryngoscope</td>
<td>An endoscope used to assist the insertion and placement of a tracheal tube in the trachea (human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is rigid, and either relay lens optics or a fiber optic system is used for image transmission.</td>
<td>36706020</td>
<td>II</td>
<td>5.0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Code</td>
<td>Class</td>
<td>CE Mark</td>
<td>Remarks</td>
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<tr>
<td>Rigid laryngoscope An endoscope used for visual examination, diagnosis, and treatment of the larynx. The device is a rigid endoscope, and has relay lens optics for image transmission.</td>
<td>15076000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Sphincteroscope An endoscope used for examination of the anal sphincter.</td>
<td>15787002</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laparoscopy kit A kit of packaged tools including devices, instruments, and other accessories necessary for laparoscopic procedures. An endoscopic device necessary for the laparoscopic procedures may be included. The kit is considered to be reusable, even if some of the accessories need to be replenished.</td>
<td>32043000</td>
<td>II</td>
<td>6-9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transcervical rigid amnioscope An endoscope inserted through the cervix and used for direct visual examination, diagnosis, and treatment of the fetus or for visual examination of the color and volume of amniotic fluid</td>
<td>32631000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transabdominal rigid amnioscope An endoscope used for visual examination, diagnosis, and treatment of the amnion. The device is inserted into the amniotic cavity through an artificial opening in the maternal abdominal wall</td>
<td>34837000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid arthroscope An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is rigid.</td>
<td>34856000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid culdoscope An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device is a rigid endoscope and relay lens optics are used for image transmission</td>
<td>34979000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid directoscope An endoscope used for visual examination and diagnosis of the larynx. The device is a rigid endoscope, and has relay lens optics.</td>
<td>35011000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid mediastinoscope An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is rigid, and relay lens optics are used for image transmission</td>
<td>35187000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid nasopharyngoscope An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a rigid endoscope and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. Relay lens optics are used for image transmission.</td>
<td>35205000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid pelviscope An endoscope used for visual examination and diagnosis of the pelvis. The device is inserted transcutaneously through an artificial opening. The device is a rigid endoscope with relay lens optics.</td>
<td>35233000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid proctoscope An endoscope used for visual examination, diagnosis, and treatment of the rectum and anus. The device is a rigid endoscope which comprises relay lens optics and a mirror with a light source at the tip.</td>
<td>35255000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Endoscope Name</td>
<td>Description</td>
<td>JMD Code</td>
<td>Section</td>
<td>Subsection</td>
<td>Applicable</td>
<td>Comment</td>
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<tr>
<td>Rigid rhinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a rigid endoscope with relay lens optics.</td>
<td>35316000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid thoracoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a rigid endoscope with relay lens optics for image transmission. Some types of device use a fiber optic bundle for image transmission, and the tip may be bent.</td>
<td>35398000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid surgical lumboscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the vertebral column, primarily the lumbar vertebrae, inserted through an artificial opening. However, devices used on the central nervous system are excluded. This product is a rigid endoscope, by which the insertion section resists the body cavity. Relay lens optics are used for image transmission.</td>
<td>35568000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid hysteroscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a rigid endoscope and certain resistance is experienced in inserting the device into the body.</td>
<td>36628000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid rhino-laryngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The device is a rigid endoscope with relay lens optics.</td>
<td>36637000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid antroscope</td>
<td>An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. The device is a rigid endoscope.</td>
<td>36647000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid esophagoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. These devices</td>
<td>36653000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid pharyngoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is rigid, and relay lens optics are used for image transmission.</td>
<td>36708000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid auditory canal endoscope</td>
<td>An extremely short endoscope used for visual examination, diagnosis, and treatment of the auditory acoustic meatus (a tube between the opening part of the ear and the eardrum). The device is usually rigid.</td>
<td>36903000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid adenoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity, used, for instance, during adenoidectomy. The device is a rigid endoscope.</td>
<td>36906000</td>
<td>II</td>
<td>5-06</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rigid sinoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a rigid endoscope with relay lens optics for image transmission. Some devices have a fiber optic bundle.</td>
<td>37180000</td>
<td>II</td>
<td>5-06</td>
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<td>Device Name</td>
<td>Description</td>
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<tr>
<td>TEM rectoscope</td>
<td>A device used for microscopic procedures and treatment of the lower intestine accessed via the anus with a special proctoscope tube (transanal endoscopic microsurgery [TEM]). It is a rigid endoscope system, and is equipped with a device to send gas to inflate the observation site and dedicated surgical devices as well as an optical observation telescope.</td>
<td>37182000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>ESDP endoscope</td>
<td>A device dedicated for the treatment of varices, such as in endoscopic subfascial dissection of incompetent perforating veins (ESDP). The device is inserted transcutaneously along the outer side of the perforating veins, through an artificial opening. The device is usually a rigid endoscope and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. The image transmission system used is one of the relay lens optics technology.</td>
<td>37183000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid lacrimal passage endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.</td>
<td>70149000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid mammary ductoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.</td>
<td>70150000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid plastic surgery endoscope</td>
<td>An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.</td>
<td>70151000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid ear endoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. The device is a rigid endoscope.</td>
<td>70153000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid salpingoscope</td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. Some devices have a fiber optic bundle.</td>
<td>70154000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Rigid stomatoscope</td>
<td>An endoscope used for visual examination of the oral cavity. The insertion section is rigid, and relay lens optics or an image fiber may be used for image transmission.</td>
<td>70155000</td>
<td>II</td>
<td>5-0</td>
<td>applicable</td>
<td>applicable</td>
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<tr>
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<td>Key</td>
<td>Type</td>
<td>Grade</td>
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<tr>
<td><strong>Ophthalmic endoscope</strong></td>
<td>An endoscope used for visual examination, diagnosis, and treatment of the eye and appendages of the eye.</td>
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<td>applicable applicable</td>
</tr>
<tr>
<td><strong>Ultrasonic flexible gastroduodenoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the upper gastrointestinal tract extending from the esophagus via the stomach to the duodenum, and the ultrasound probe is used for the examination of mucus membranes, the gall bladder, pancreas, stomach, and surrounding organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.</td>
<td>70156000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic rigid laparoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the abdominal area, and the ultrasound probe for the examination of the abdominal area. The device is inserted through an artificial opening in the abdominal wall. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. The device is a rigid endoscope with relay lens optics, or a videoscope with a solid-state image sensing device.</td>
<td>36963000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic flexible duodenoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the upper gastrointestinal tract extending from the esophagus via the stomach to the duodenum, and the ultrasound probe is used for the examination of mucus membranes, the gall bladder, pancreas, stomach, and surrounding organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.</td>
<td>37223000</td>
<td>II</td>
<td>5-6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic flexible colonoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the lower gastrointestinal tract, from the rectum, via the colon, to the cecum, and the ultrasound probe is used for the examination of mucus membranes and other organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.</td>
<td>38807000</td>
<td>II</td>
<td>5-6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic flexible laparoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the abdominal area, and the ultrasound probe for the examination of the abdominal area. The device is inserted through an artificial opening in the abdominal wall. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.</td>
<td>70157000</td>
<td>II</td>
<td>6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasonic flexible bronchoscope</strong></td>
<td>An endoscope with a build-in ultrasound probe: the endoscope is used for visual examination, diagnosis, and treatment of the bronchi and lungs, and the ultrasound probe for examination of the bronchi, lungs, and surrounding organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device. Some devices may use a fiber optic bundle together with a solid-state image sensing device.</td>
<td>70158000</td>
<td>II</td>
<td>5-6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ultrasound endoscopic observation system</strong></td>
<td>A dedicated system used for endosonographic imaging. The device consists of an endoscopic ultrasound device and ultrasound imaging device. The system supports a variety of transducers and associated application software packages, used for the collection, display and analysis of ultrasonographic information. Typical uses include:</td>
<td>70159000</td>
<td>II</td>
<td>5-6</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Endoscope light source/processing unit with air/water supply function</strong></td>
<td>A dedicated external power source device, designed to function as both a light source and a processing unit intended for use together with endoscopes (primarily video endoscopes). This device provides light for viewing the surgical fields and body cavities, and receives the electronic image signals for processing into signals that can be displayed on a monitor.</td>
<td>34540002</td>
<td>II</td>
<td>11</td>
<td>applicable applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Line-powered endoscope light source with air/water supply function</strong></td>
<td>A dedicated, external power source that provides light for viewing body cavities when using rigid or flexible endoscopes (e.g., laparoscopes and gastroscopes) and their accessories. The device transmits its light through a fiber-optic cable that connects the endoscope to the site of observation and intervention while minimizing tissue heating.</td>
<td>35158002</td>
<td>II</td>
<td>11</td>
<td>applicable applicable</td>
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<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Subtype</td>
<td>Applicable</td>
<td>Remarks</td>
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<tr>
<td>Battery-powered endoscope light source with air/water supply function</td>
<td>A dedicated battery-powered device that provides light for viewing surgical field and body cavities when using rigid or flexible endoscopes, (e.g., laparoscopes and gastroscopes) and their accessories. The device transmits its light through a fiber-optic cable that connects the endoscope to the site of observation and intervention, while minimizing tissue heating. Depending on the built-in optical filters, some devices may generate infrared light, ultraviolet light, or visible light within a specific wavelength range. The device can supply air or water.</td>
<td>35906002</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Hysteroscopic gas distension unit</td>
<td>A dedicated device used to inject pressure-adjusted gas into the uterine cavity to distend the uterus. This device makes it possible to secure a wide area in the uterine cavity for examinations and surgery. It maintains gas pressure in equilibrium through gas leakage correction.</td>
<td>12144000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Bipolar endotherapy coagulator</td>
<td>A special electrosurgical unit used during endoscopy in high-frequency endoscopic electrosurgery. This device destroys the tissue between 2 contact faces of the device with high temperature by detecting the high-frequency current in that tissue.</td>
<td>32684000</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Unipolar endotherapy coagulator</td>
<td>A special electrosurgical unit used during endoscopy in high-frequency electrosurgery. This device destroys the tissue between the electrode tip of the device and the plate attached to the patient's external body surface with high temperature by detecting the high-frequency current in that tissue.</td>
<td>33596000</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscopic electrosurgical unit</td>
<td>A dedicated electrosurgical unit designed to be used with an endoscope and dedicated endoscopic devices in endoscopic treatment. It is specifically designed to generate high-frequency energy inside the body via the endoscope or the endoscope system when used with the endoscopic electrode.</td>
<td>33602000</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Arthroscopic fluid distension unit</td>
<td>A dedicated device used to distend the tissue around the joint where an arthroscopy is being performed (e.g., the knee or shoulder joint). The cavity is filled with fluid to extend the tissue around the site, which facilitates viewing and intervention with an arthroscope. The device may usually be used to irrigate surgically removed bone, cartilage, and other tissue debris, and remove body fluids from the site.</td>
<td>36003000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope irrigation/aspiration unit</td>
<td>A dedicated endoscopy device intended for perfusion and aspiration (washing effect) with fluids to facilitate endoscopic viewing and intervention in body cavities or the lumen of a device. The device should be used with a suitable endoscope and its accessories.</td>
<td>36023000</td>
<td>II</td>
<td>6,11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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<tr>
<td>Hysteroscopic fluid distension unit</td>
<td>A dedicated endoscopy device intended to inject fluids into the uterine cavity to dilate the uterus, in order to facilitate hysteroscopic viewing and intervention. The device also helps to provide a wide space for intervention. The device may also be used to wash resected tissues and remove body fluid from around the intervention site.</td>
<td>36122000</td>
<td>II</td>
<td>2,11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrosurgical unit with endotherapy monitor/shield</td>
<td>A dedicated device designed to be connected to an appropriate electrosurgical unit in order to manage leakage of high frequency current from the active electrode used with the endoscope, the endoscope system or dedicated endoscopic treatment device in endoscopic treatment (e.g., laparoscopic surgery). It is specifically designed to monitor and manage the leakage current during high-frequency endoscopic electrosurgery.</td>
<td>36152000</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Arthroscopic gas distension unit</td>
<td>A dedicated device used to inflate the tissues around the joint (e.g., knee joint, shoulder joint) for arthroscopy. With this device, inert gas is injected into the space to inflate the tissues around the treatment site, which makes observation and treatment easier with an arthroscope.</td>
<td>36677000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope air supply pump</td>
<td>A device that supplies air via the endoscope to prevent condensation/dew condensation on the lens, or to extend the space at the tip of the endoscope, in order to provide the desired field of view, and visibility to allow intervention.</td>
<td>36750012</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope water supply system</td>
<td>An endoscopic device intended to supply water to facilitate endoscopic viewing in body cavities, or the lumen of another device. The device should be used with a suitable endoscope and its accessories.</td>
<td>36500022</td>
<td>II</td>
<td>2,11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope air and water supply system</td>
<td>An endoscopic device intended to supply air or water to facilitate endoscopic viewing, or intervention in body cavities, or the lumen of another device. The device should be used with a suitable endoscope and its accessories.</td>
<td>36500032</td>
<td>II</td>
<td>2,11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope contour detector device</td>
<td>A device intended for use in displaying on the monitor screen the 3-dimensional morphology of the endoscope inserted in the lumen, to aid endoscope insertion. This display is achieved by extracorporeally detecting the magnetic field generated by the endoscope using a built-in magnetic generator, or from a probe that includes a built-in</td>
<td>70161000</td>
<td>II</td>
<td>10-10</td>
<td>applicable</td>
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<td>Medical Device Description</td>
<td>Number</td>
<td>Category (II, III)</td>
<td>Applicability</td>
<td>Remarks</td>
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<tr>
<td>Endoscopic irrigation/aspiration probe A probe intended to be connected to a dedicated device for perfusion and aspiration (washing effect) with fluids to facilitate endoscopic viewing and intervention in body cavities or within the lumen of a device. Some devices may have electrocautery capabilities. The device is intended for single-use.</td>
<td>70162000</td>
<td>II</td>
<td>9,11</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable electro surgical endoscopic snare A device intended for use in ligating, cauterizing, and severing tissue and polyps, employing a high frequency current during endotherapy. The device consists of an insulated introducer sheath, snare loop (attached to the tip of the sheath), manipulating wire (connected to the loop and handle), and a handle (controlling the manipulating wire). The proximal end of the manipulating wire is connected to a high frequency supply device.</td>
<td>35623000</td>
<td>II</td>
<td>6·1,9</td>
<td>N/A</td>
<td></td>
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</tr>
<tr>
<td>Endoscopic working guide An endoscopy component which consists of several elements that are needed for it to function. The device is used to assist the entry of the endoscopic electrode into an appropriate endoscope. The device can activate the electrode's cutting path actively or</td>
<td>37085000</td>
<td>II</td>
<td>6,9</td>
<td>N/A</td>
<td></td>
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</tr>
<tr>
<td>Reusable active endotherapy device A device used for endoscopic treatment (e.g., ablation and coagulation of the tissues) utilizing electricity (including energy sources such as high-frequency, electromagnetism, ultrasound and laser) or external driving forces. Generally the device consists of probe electrodes inserted through the working channel or other route, and a generator supplying energy to be transmitted to the tip of this device. It may be used via a supporting device. This device is reusable.</td>
<td>38816000</td>
<td>II</td>
<td>6·1,9</td>
<td>N/A</td>
<td></td>
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</tr>
<tr>
<td>Single-use active endotherapy device A device used for endoscopic treatment (e.g., ablation and coagulation of the tissues, smoke emission) utilizing high-frequency, electromagnetism, ultrasound, laser and other energy. The device consists of probe electrodes inserted through the working channel or other route, and a generator supplying energy to be transmitted to the tip of this device. It may be used via a supporting device.</td>
<td>38817000</td>
<td>II</td>
<td>6,9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Single-use electro surgical endoscopic snare A device intended for use in ligating, cauterizing, and severing tissue and polyps, employing a high frequency current during endotherapy. The device consists of an insulated introducer sheath, snare loop (attached to the tip of the sheath), manipulating wire (connected to the loop and handle), and a handle (controlling the manipulating wire). The proximal end of the manipulating wire is connected to a high frequency supply device.</td>
<td>38827000</td>
<td>II</td>
<td>6,9</td>
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<tr>
<td>Reusable high-frequency current procedure endoscopic active instrument Active electrodes that perform incision and coagulation of tissues are deployed within the endoscope, making use of high-frequency current: a probe is used to perform incision and coagulation, conducting electricity and heating up a heating element: together with electrically conductive cables, as well as associated accessories. A device intended for</td>
<td>70164010</td>
<td>II</td>
<td>9</td>
<td>N/A</td>
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<tr>
<td>Single-use high-frequency current procedure endoscopic active instrument Active electrodes that perform incision and coagulation of tissues are deployed within the endoscope, making use of high-frequency current: a probe is used to perform incision and coagulation, conducting electricity and heating up a heating element: together with electrically conductive cables, as well as associated accessories. A device intended for</td>
<td>70164020</td>
<td>II</td>
<td>9</td>
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<tr>
<td>Electrosurgical endoscopic thermal diode A dedicated device intended for use with an endoscope during endotherapy. The device has a built-in thermal diode at the distal tip. The device is used for occluding the uterine tubes for female sterilization, or coagulation of bleeding tissues. Some devices may have a high-frequency current supply device connected to it.</td>
<td>37155000</td>
<td>II</td>
<td>6,9</td>
<td>N/A</td>
<td></td>
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</tr>
<tr>
<td>Endoscopic resection device A device that is inserted into a body cavity together with an endoscope or on its own, to cut or resect tissues using an electrically powered or pneumatically powered rotating/sliding severing blade. Some devices may be used under direct vision, or under the operating microscope, or have perfusion/suction capabilities</td>
<td>35326002</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
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</tr>
<tr>
<td>Single-use artificial orifices endotherapy cannula A device used to deliver agents or contrast media into body cavities through an artificial opening during endoscopic examination, for the purpose of either diagnosis or treatment. The device is intended for single-use.</td>
<td>38814002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
<tr>
<td>Single-use artificial orifices endotherapy dilator A device, either rigid rod or flexible tube, used to dilate lumens or body cavities, to enable or facilitate insertion of endoscopic devices. Such dilation may be performed transcutaneously (through the cutaneous layers) via an artificial opening into the human body. The device is intended for single-use.</td>
<td>38821002</td>
<td>II</td>
<td>6</td>
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<tr>
<td>Device Description</td>
<td>Code</td>
<td>Level</td>
<td>Quantity</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Fetal blood sampler</td>
<td>12662000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Single-use artificial orifices non-active endotherapy device</td>
<td>38819000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<td></td>
</tr>
<tr>
<td>Single-use infection-prevention endoscopic sheath for artificial orifices</td>
<td>70173000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<td></td>
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<tr>
<td>Bronchoscope ventilation sheath</td>
<td>70174000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
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<tr>
<td>Laryngostroboscope</td>
<td>12294000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laparoscopic lesion lifting device</td>
<td>70175000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Artificial orifices endoscope defroster</td>
<td>70177000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Multiphasic health testing system</td>
<td>70178000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Biofeedback system</td>
<td>10396000</td>
<td>II</td>
<td>10-③</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Penile tumescence transducer</td>
<td>17442000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Long-term gastric pH data recorder</td>
<td>36965000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Dental diagnostic intraoral camera</td>
<td>70180000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
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<tr>
<td>Pelvic examination kit</td>
<td>34122000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<td></td>
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<tr>
<td>Single-use tissue biopsy needle</td>
<td>12734010</td>
<td>II</td>
<td>6</td>
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<td></td>
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<tr>
<td>Aspiration tissue biopsy needle kit</td>
<td>12734020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>E/M Code</td>
<td>Category</td>
<td>Risk Level</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Single-use cholangiographic needle</td>
<td>An elongated, edged instrument used in injection of contrast media for cholangiography. The device is intended for single-use.</td>
<td>12739002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use subcutaneous needle</td>
<td>An elongated, edged, hollow tube used together with an injector, secondary pharmacotherapy kit, or venous access kit (for example, blood collection adapter and holder) for administration or withdrawal of liquids. The device is intended for single-use.</td>
<td>12745002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use intra-arterial needle</td>
<td>An elongated, edged, hollow tube used to puncture an artery. The device is usually made of metal and for single-use.</td>
<td>12747012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use tine test needle</td>
<td>An elongated, sharp needle used to make multiple punctures simultaneously during tests (for example, the tine test for tuberculosis). The device is intended for single-use.</td>
<td>15679012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tine test/vaccine needle</td>
<td>A elongated, sharp needle or needles with different tip shapes (for example, bifurcated) that are used to make multiple punctures simultaneously (e.g., the tine test for tuberculosis or during smallpox vaccination). The device is intended for single-use.</td>
<td>15679022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use filter needle</td>
<td>An elongated, edged instrument with an integrated filter for filtration of the injection solution. The device is intended for single-use.</td>
<td>16266002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use subcutaneous injection/infusion port needle</td>
<td>An elongated, edged, hollow tube that is attached to a syringe and inserted subcutaneously for drug injection or used to inject drugs into a line. The device is intended for single-use.</td>
<td>17180002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use injection needle</td>
<td>An elongated, sharp metal needle inserted into the skin to inject or withdraw fluids. The device is intended for single-use.</td>
<td>30889000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use fistula needle</td>
<td>A long, thin, sharp, hollow device for single-use to drain fluids from a fistula.</td>
<td>32111002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use ophthalmic cannula</td>
<td>A sterilized tube used to collect/aspirate intraocular contents or to inject perfusate into the eye in ophthalmic surgery. The device is intended for single-use.</td>
<td>34899012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use ophthalmic surgery cannula with tube</td>
<td>A cylindrical device that is equipped with a tube and used to inject perfusate (e.g., irrigation fluid) or aspirate intraocular contents in ophthalmic surgery. The device is intended for single-use.</td>
<td>34899022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use ophthalmic surgical cannula</td>
<td>A cylindrical device used to inject perfusate (e.g., irrigation fluid) or aspirate intraocular contents in ophthalmic surgery. The device is intended for single-use. Some of these devices have a round, flat, or hook-shaped tip. There may also be a sleeve at the tip.</td>
<td>34899032</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use blood collecting needle</td>
<td>A single-use needle that constitutes part of a blood collection kit. The needle is attached to a holder and has a shape that punctures directly into the human body to collect blood and a shape that connects to a winged needle without having a needle that punctures into the human body.</td>
<td>35209002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Item Description</td>
<td>Definition</td>
<td>Code</td>
<td>Group</td>
<td>Location</td>
<td>Status</td>
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<tr>
<td>Single-use blunt needle</td>
<td>A long, thin device with a blunt curved tip so as to prevent damage to delicate structures during probing inside the body.</td>
<td>35210000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use aspiration needle</td>
<td>An elongated, edged, hollow tube used to withdraw fluids from a body cavity or collect biopsy specimens. The device is intended for single-use.</td>
<td>35886000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use manually-operated lancet</td>
<td>A small, sharp-tipped instrument for skin puncture, used to collect blood or to drain the content of pus (Note 1) or furuncle (Note 2). The device may be shaped like a needle or sword. The device is intended for single-use.</td>
<td>37466000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Introduction needle</td>
<td>A puncture device that aids insertion of a needle, catheter, or wire into the body for therapy or diagnosis.</td>
<td>70194000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Prefilled syringe double-edged needle</td>
<td>An instrument that has a metal or plastic needle on both ends and is used to penetrate a rubber stopper (e.g., of a prefilled syringe) for administration or mixing of drug solutions in the container. The device is intended for single-use.</td>
<td>70195000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use intrabone injection needle</td>
<td>A needle with an elongated lumen used to puncture bone to collect tissue or inject drug solutions. The device is commonly made of metal or plastic and for single-use.</td>
<td>70197000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use infusion/drainage needle</td>
<td>A long, thin, sharp, metal needle used to pierce the skin in order to inject or drain fluids. Besides a long, thin, sharp, hollow needle, needles with various configurations such as bifurcated tip are available. This device is for single-use.</td>
<td>70198000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Ophthalmic needle</td>
<td>A hollow needle used to inject drug solutions into the eye or to aspirate intraocular fluids into the syringe during eye surgery (for example, cataract surgery). The device is either straight or curved. The device is intended for single-use.</td>
<td>70200000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Dental injection needles</td>
<td>A device that is made up of an elongated, hollow metal tube with a sharp tip and a needle hub and is primarily used with a dental cartridge syringe for administration of local anesthetic agents.</td>
<td>12740000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Drug/vaccine injection needle</td>
<td>A device used for parenteral administration of a drug in a cartridge. The cartridge may be integrated with a pen injector, or is either attached or inserted into a pen injector for use. The device is used by patients who regularly self-administer drugs such as insulin and</td>
<td>44127010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use endoscopic sclerotherapy injection needle</td>
<td>A device that is used with a special endoscope for endoscopic sclerotherapy to inject a drug into the mucosa or a blood vessel. The tip of the soft tube has an injection needle and a syringe connector at the other end. The device is intended for single-use</td>
<td>36076002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Single-use endoscopic injection needle</td>
<td>A device that is used with a special endoscope in endoscopic surgery to inject a drug into the mucosa or a blood vessel, for purposes such as hemostasis and sclerotherapy. The tip of the flexible tube has an injection needle and a syringe connector at the other end. The device is intended for single-use</td>
<td>38825000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Percutaneous ethanol injection needle</td>
<td>An elongated, edged, hollow tube used to inject ethanol percutaneously into hepatocellular carcinoma tumors to induce necrosis. The device comes as a kit with a guide needle to be</td>
<td>44127020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>6 applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>II</td>
<td>#</td>
<td>Applicable</td>
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<tr>
<td>Contrast medium injection needle</td>
<td>A thin, edged instrument that is connected with a contrast-filled syringe for injection of contrast media used in computerized tomography (CT). The device is sterilized and intended for single-use.</td>
<td>44127030</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Syringe with general-purpose needle</td>
<td>A device used to inject or withdraw a fluid or gas. The device is normally made of glass or plastic and consists of a container with a scale and a plunger. The device is often used to administer drugs or collect blood.</td>
<td>13929002</td>
<td>II</td>
<td>2,6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood gas syringe</td>
<td>An instrument comprising a tube and plunger and used with a needle to collect arterial blood. The device is usually made of plastic or glass and can collect blood without exposing it to the air.</td>
<td>16785000</td>
<td>II</td>
<td>2,6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Active device connected anaesthesia syringe</td>
<td>A hollow, plastic cylinder-shaped device with an injection plunger. The device is used for administration (injection) of substances such as anesthetics. The device is connected to an active device.</td>
<td>35387002</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Needleless cartridge hypodermic syringe</td>
<td>A device consisting of a metal tube and a plunger. Before using the device, a sealed glass cartridge containing medication is loaded into the device from its proximal end. The device has a dedicated nozzle that pushes in the contents of the cartridge percutaneously.</td>
<td>36279000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hypodermic syringe with safety-needle cartridge</td>
<td>A device consisting of a metal tube and a plunger. Before using the device, a sealed glass cartridge containing medication is loaded into the device from its proximal end. The device uses a non-exposed needle with protection for subcutaneous injection protection.</td>
<td>36280000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Drug/vaccine injection syringe</td>
<td>A device used for intramuscular (IM) or subcutaneous injection of a pharmaceutical or vaccine into the human body using a standard plunger syringe with an appropriate needle. A pharmaceutical or vaccine for injection is drawn into a prefilled syringe which is placed on the device.</td>
<td>12132000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Loss of resistance epidural localization syringe</td>
<td>A device used in the loss of resistance (LOR) method in epidural anesthesia. It consists of a syringe and a plunger, and is usually made of plastic or glass.</td>
<td>70201002</td>
<td>II</td>
<td>2,6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Temporary use anesthesia puncture needle</td>
<td>A hollow device for percutaneous nerve block. Some needles have an insulated shaft, others have a terminal which is connected to an electrode, and others are sharp and hollow. The device is for temporary placement and also for single-use. The device cannot be used on the central nervous system.</td>
<td>70203012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Puncture needle with port</td>
<td>A puncture needle with a side port for the guidewire channel, used to insert a vascular catheter.</td>
<td>70203022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Plastic cannula sterile puncture needle</td>
<td>An arterial or venous indwelling needle made up of a plastic cannula and a metal needle.</td>
<td>70204010</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Plastic cannula abdominal puncture needle</td>
<td>A device comprising a plastic cannula and a metal needle, used to puncture a body cavity or organ to drain fluids or inject drug solutions.</td>
<td>70204020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dialysis indwelling needle</td>
<td>A non-metal indwelling needle placed at the puncture site for hemodialysis.</td>
<td>70204030</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ultrasonic aspiration biopsy kit</td>
<td>The biopsy needle and other supplies required for image-guided aspiration biopsy of a tissue. The distal tip of the needle must remain clearly visible on the image.</td>
<td>10403000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Injection needle set</td>
<td>A device made up of an injection needle, syringe, and tube or three way stopcock and used for percutaneous injection of solutions (e.g., into an organ) or for mixing of drug solutions.</td>
<td>70205000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Application</td>
<td>Notes</td>
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<tr>
<td>Nerve exploration set</td>
<td>A set of needles used for nerve search guided by muscle contraction and for local injection of drug solutions, and electrode catheters, etc.</td>
<td>70206000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Marker insertion set</td>
<td>A device consisting of a puncture needle, an introducer needle, and a marker and used for placement of a metal marker or pigment injection into a tumor or other tissues. Not all of the components are included in some products.</td>
<td>70207000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laser irradiation therapy set</td>
<td>A set of puncture needles, a metal wire(s), a metal pipe(s), etc. which are used for laser irradiation therapy.</td>
<td>70208010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laser irradiation therapy kit</td>
<td>A kit includes a puncture needle, a guide wire, and a guiding sheath for guiding probes (used for laser irradiation therapy, for example). Not all of the components are included: in some products, two or more of components are integrated into one</td>
<td>70208020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transvaginal drug solution injection needle</td>
<td>A device consisting of a needle and a tube used to inject a drug solution transvaginally.</td>
<td>70210000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Brachytherapy puncture set</td>
<td>A device is a puncture needle for insertion of a radiation source into the body (e.g., a tumor) and made up of a stylet and cannula.</td>
<td>70211000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Electromagnetic wave coagulation therapy needle</td>
<td>A puncture needle used in microwave coagulation therapy to protect electrodes, etc. The device has a hollow metal or plastic tube. This tube may be insulated and have a sharp tip. The device may come with an extension tube.</td>
<td>70212000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Electromagnetic wave coagulation therapy kit</td>
<td>A package containing a puncture needle and other necessary tools, such as an extension tube, for protection of electrodes, etc. during microwave coagulation therapy. The device has a hollow metal or plastic tube. This tube may be insulated and have a sharp tip.</td>
<td>70213000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thermotherapy needle</td>
<td>A puncture needle used for protection of an internal temperature sensor, etc. during heat therapy. The device has a hollow metal or plastic tube, with or without a closed end. The device may also come with a stylet or some other tools.</td>
<td>70214000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thermotherapy kit</td>
<td>A package consisting of devices necessary for thermotherapy, including puncture needles and a stylet used as a protective device for the sensor for measurement of deep temperature. It has a metal or plastic hollow tube, and the tip may be closed.</td>
<td>70215000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use arthrogram kit</td>
<td>A kit of single-use devices and supplies used to visualize the joint radiographically after injection of contrast media into the joint space.</td>
<td>15316002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bone marrow biopsy kit</td>
<td>A kit used for aspiration of tissue during a bone marrow biopsy. The kit includes a single-use biopsy needle and other necessary tools.</td>
<td>16833000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Renal biopsy kit</td>
<td>A kit for renal biopsy. The kit includes a biopsy needle and other necessary tools.</td>
<td>16834000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Endometrial sampling kit</td>
<td>A kit consisting of the appropriate devices to create sample slides and smear preparations, including syringes, needles, and aspirators, swabs, sample collectors for obtaining endometrial tissue. This is used to collect and prepare Pap smears samples in a medical institution. This kit is for single-use.</td>
<td>11531000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Level</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Soft tissue biopsy kit</td>
<td>A kit for collection of soft biological tissues. The kit includes a biopsy needle and other necessary tools.</td>
<td>16835010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Powered soft tissue biopsy kit</td>
<td>A kit consisting of various components including biopsy needles and other necessary items that are used to collect the biological soft tissue of the target site. This device has an electrically operated control unit.</td>
<td>16835020</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use bone marrow collection/transfusion set</td>
<td>A kit containing a bag, filter, tube and adapter that are to be combined for collection or filtration of bone marrow. The device is intended for single-use.</td>
<td>33984002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Lung biopsy kit</td>
<td>A kit consisting of various instruments, including single-use biopsy needles, and other necessary items that are used to aspirate tissue samples during transdermal lung biopsy.</td>
<td>38562000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Brain biopsy kit</td>
<td>A kit consisting of various components, including a single-use brain biopsy needle(s), and other necessary items that are used to perform brain stereotactic biopsy.</td>
<td>38563000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use lumbar puncture kit</td>
<td>A kit used for puncture of the lumbar spine and collection of spinal fluid. The kit includes single-use instruments and other materials. The package usually contains a spinal needle and tube for spinal fluid.</td>
<td>12404002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use lumbar puncture needle</td>
<td>A needle with a stylet used during a lumbar puncture to collect spinal fluid for diagnostic testing. The device is intended for single-use.</td>
<td>34583002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use pneumoperitoneal needle</td>
<td>An elongated needle that is used to inject or drain gas from the peritoneal cavity. The device is intended for single-use.</td>
<td>12750002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use automatic lancet</td>
<td>An instrument for collection of blood from capillary vessels in the fingertip or ear lobe. The built-in needle automatically pops out and pierces the skin to the preset depth. This enables sampling of a small amount of blood for testing. The device is intended for single-use.</td>
<td>37243002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Reusable manually-operated lancet</td>
<td>A small device with a sharp tip (needle-like) used to puncture the skin for blood sampling or drainage of the bursa or ganglion. This device is reusable.</td>
<td>37244000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Esophageal varices sclerotherapy injector</td>
<td>A puncture instrument used together with an endoscope for injection of a sclerosing agent in sclerotherapy of esophageal varices. It consists of a needle, syringe, flexible tube, and connector among others.</td>
<td>70217000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Thoracic trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the chest cavity during chest surgery. A trocar assembly can be introduced in combination with a compatible sleeve filling lumen of the trocar. Removing the trocar after puncture</td>
<td>70218000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Instrument Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Abdominal trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working channel into the body cavity.</td>
<td>14155000 II 7</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Amniotic trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall and amniotic cavity of a pregnant woman for endoscopic observation of the fetus.</td>
<td>14156000 II 7</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Gallbladder trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall to access the gallbladder. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working channel into the body cavity.</td>
<td>14159000 II 7</td>
<td>applicable</td>
<td>–</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastro-urology trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall. The device is normally used with a sleeve. Removing the trocar after puncture creates a working channel into the body cavity.</td>
<td>32021000 II 6</td>
<td>applicable</td>
<td>–</td>
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</tr>
<tr>
<td>Gastrostomy trocar</td>
<td>A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall and perform gastrostomy. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working channel into the body cavity.</td>
<td>70219000 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Single-use amniocentesis needle</td>
<td>A needle used for transabdominal surgical puncture, for collection of amniotic fluid or the fluid contained in the umbilical cord. The device is intended for single-use.</td>
<td>70220000 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Single-use amniocentesis kit</td>
<td>A pre-packaged kit for transabdominal surgical puncture, used for collection of amniotic fluid or the fluid contained in the umbilical cord. The kit contains a needle, syringe, blood collection tube, and disinfection materials, etc.</td>
<td>35496000 II 6</td>
<td>applicable</td>
<td>–</td>
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</tr>
<tr>
<td>Single-use trocar sleeve</td>
<td>A plastic sleeve used together with a trocar during puncture of a body cavity. Removing the trocar after puncture creates a working channel into the body cavity. The sleeve may have a shut-off valve or port for supplying gas or fluid. Some products do not require a shut-off valve.</td>
<td>37148002 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invasive single-use trocar sleeve fixation device</td>
<td>A device that is attached to a trocar sleeve for invasive fixation of the sleeve to the abdominal wall. The device is intended for single-use.</td>
<td>70222000 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Single-use trocar guide rod</td>
<td>A small metal or plastic rod guiding a large (10 to 20 mm in diameter) trocar sleeve, in order to expand the working channel created in the body. This rod is inserted into a trocar sleeve, and the sleeve is withdrawn while keeping airtightness of the opening. A special dilator to which a large sleeve is attached is inserted outside the rod and this assembly is inserted.</td>
<td>37149002 II 6</td>
<td>applicable</td>
<td>–</td>
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</tr>
<tr>
<td>Single-use trocar sleeve dilator</td>
<td>A hollow dilator with a tapered tip. It is used for a significant dilatation of the working channel (10 to 20 mm in diameter). The tapered tip enables smooth insertion of a large trocar sleeve. The dilator is inserted outside the guide rod and used to displace the skin.</td>
<td>37151002 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Single-use subcutaneous tunneller</td>
<td>A surgical instrument that is usually made of metal including stainless or polymeric material and used to create an interconnected channel or a tunnel under the skin for insertion of a tube or catheter. The device is intended for single-use.</td>
<td>35950002 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Urological needle guide</td>
<td>A device used to assist needle insertion into the urinary tract for treatment or diagnosis.</td>
<td>70227000 II 6</td>
<td>applicable</td>
<td>–</td>
<td></td>
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</tr>
<tr>
<td>Short-term use jejunostomy catheter</td>
<td>A flexible tube used for a short term to create a fistula between the abdominal wall and jejunum.</td>
<td>10731002 II 7</td>
<td>applicable</td>
<td>–</td>
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<td></td>
</tr>
<tr>
<td>Short-term use enteral feeding kit</td>
<td>A package of materials used for a short term for enteral nutrition.</td>
<td>11677002 II 5-7</td>
<td>applicable</td>
<td>–</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transesophageal enteral feeding tube</td>
<td>A long, flexible, radiopaque tube (or non-opaque tube with a separate radiopaque line) to be placed in the stomach via the nasopharynx or esophagus, for enteral nutrition.</td>
<td>16798000 II 5-7</td>
<td>applicable</td>
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</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Short-term use enterostomy feeding tube</td>
<td>A hollow tube to be surgically placed in the stomach, duodenum, or jejunum for short-term enteral nutrition.</td>
<td>16799002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use gastrostomy feeding tube</td>
<td>A hollow tube to be surgically placed in the stomach for short-term enteral nutrition. This device does not allow back-flow, and its proximal tip remains flat to the abdominal skin and creates no protrusion.</td>
<td>35419002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Jejunostomy feeding tube</td>
<td>A hollow tube to be surgically placed in the jejunum for enteral nutrition.</td>
<td>38564000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use gastrostomy button</td>
<td>A short tube inserted into the stomach percutaneously, for short-term enteral nutrition.</td>
<td>38565002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal tube</td>
<td>A single-lumen or double-lumen, flexible plastic tube to be placed in the stomach, duodenum, or jejunum for aspiration or enteral nutrition.</td>
<td>14202000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use nasogastric tube</td>
<td>A flexible, plastic tube to be placed for a short term in the stomach via the nasopharynx or esophagus for removal of gastric contents, administration of drugs, or enteral nutrition.</td>
<td>14221012</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use nasal/oral gastric tube</td>
<td>A flexible, plastic tube to be placed for a short term in the stomach, duodenum, or jejunum via the nasopharynx or mouth and esophagus, for administration of drugs or enteral nutrition.</td>
<td>14221022</td>
<td>II</td>
<td>5-7,5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Stomach evacuator tube</td>
<td>A single-lumen tube inserted into the stomach via the mouth, for removal of gastric contents.</td>
<td>14230000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Appetite-suppressing gastric balloon</td>
<td>A balloon to be inserted into the stomach and inflated there to suppress appetite. The indwelling balloon creates a false sense that the stomach is almost full. The balloon is inserted through a catheter, and placed until the desirable effect is obtained. Usually it is made of polymeric materials and deteriorates over time.</td>
<td>17202000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Mercury balloon single lumen tube</td>
<td>A tube used for infusion of solutions, drainage, splinting and bleeding compression in the gastrointestinal tract.</td>
<td>32058000</td>
<td>II</td>
<td>5-7,7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use esophageal tube</td>
<td>A hollow tube used for a short term to achieve hemostasis of a bleeding varix. The device usually comes with two balloons (one for the stomach and the other for the esophagus). Some may only come with just one, or three or more balloons.</td>
<td>35416002</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use sterile gastroesophageal tube and catheter</td>
<td>A set comprising a tube and catheter inserted into the esophagus or stomach for a short period for sampling of gastric juice, injection of drug solutions, lavage, or diagnosis. Some products also include a syringe and connector etc</td>
<td>70232000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Esophageal varices sclerotherapy endoscopic fixation balloon</td>
<td>A balloon catheters used to fix an endoscope in the esophagus during sclerotherapy for esophageal varices. The device consists of a balloon and flexible tube. Some products also include a syringe and connector etc</td>
<td>70233000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Esophageal varices sclerotherapy hemostatic balloon</td>
<td>A balloon catheter used to achieve hemostasis of the puncture site during sclerotherapy for esophageal varices.</td>
<td>70234000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Suture anchor</td>
<td>A device used to approximate the gastric wall to the abdominal wall to facilitate gastrostomy.</td>
<td>70235000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rectal tube</td>
<td>A tube inserted into the rectum for diagnosis or therapy.</td>
<td>14227000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Barium enema kit</td>
<td>A kit consisting of items used for injecting a barium suspension via the rectum into the large intestine for performing enema examination.</td>
<td>16514000</td>
<td>II</td>
<td>5-7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Number of Uses</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Intestinal decompression tube</td>
<td>A hollow tube to be placed in the intestine to reduce the increased pressure that may occur before and following bowel obstruction.</td>
<td>35415010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Short-term use infant enteral feeding kit</td>
<td>A kit of parts to be assembled for short-term enteral nutrition in infants.</td>
<td>36044002</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Gastrointestinal guidewire</td>
<td>A guidewire used in gastrointestinal (including bile duct) procedures (excluding probes).</td>
<td>70236000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Intestinal balloon catheter</td>
<td>A balloon used to dilate a narrowed area of the gastrointestinal tract (duodenum and lower GI tract) or to fix the distal end of an endoscope.</td>
<td>70237000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Intestinal tube</td>
<td>A hollow tube to be placed in the gastrointestinal tract (intestine, for example) for a variety of purposes such as depressurization, draining, lavage, and injection of drug solutions</td>
<td>35415020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Short-term use biliary/pancreatic duct catheter</td>
<td>A flexible tube used for a short term for biliary tract drainage, splinting of the bile duct during therapy, or supporting the bile duct to prevent stenosis. The device is sometimes used for pancreatic duct drainage.</td>
<td>10696012</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Short-term use biliary catheter</td>
<td>A flexible tube used for a short term for biliary tract drainage, splinting of the bile duct during therapy, or supporting the bile duct to prevent stenosis.</td>
<td>10696022</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Biliary drain</td>
<td>A flexible tube made of natural rubber or silicone and used to drain bile during biliary tract surgery. The device may have a side hole(s).</td>
<td>11307000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cholangiography catheter</td>
<td>A flexible tube used to inject contrast media into the gallbladder, bile duct, or pancreatic duct for enhanced radiography.</td>
<td>16429000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Biliary manometric catheter</td>
<td>A flexible tube designed to measure pressure in the biliary system.</td>
<td>36181000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Introducer for bile duct stent</td>
<td>An introducer used to insert a biliary stent. The device is intended for single-use.</td>
<td>70238000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use endoscopic lithectomy forceps</td>
<td>A device that is used with a dedicated endoscope to hold and remove stones during endoscopic therapy. The device is made of an elongated shaft and a wire basket at the tip.</td>
<td>37141002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Biliary dilatation catheter</td>
<td>A catheter used to dilate a narrowed bile duct.</td>
<td>70239000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Gallstone removal catheter set</td>
<td>A catheter or a set of devices used in combination of the catheter which inserted into the biliary tract together with an endoscope, for removal of bile duct stones. The catheter inserted into the biliary tract device consists of a sheath, and a wire basket to capture bile duct stones etc.</td>
<td>70240000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Lithectomy balloon catheter</td>
<td>A device used alone or with an endoscope for removal of stones. It comprises an elongated sheath and a balloon at the tip, designed to trap stones.</td>
<td>70241000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
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<td>Applicable</td>
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<tr>
<td>Lithotripsy forceps</td>
<td>A device used alone or with an endoscope for crushing and removal of stones. The device consists of an elongated sheath and a wire basket at the tip that crushes and captures stones.</td>
<td>70242000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Barium enema rectal catheter</td>
<td>A flexible tube used to inject barium into the lower GI tract via the rectum, for enhanced radiography. Rubber or plastic variants are also used in colonoscopy. There are other variants that come with an indwelling balloon made of silicone, used for testing incontinence.</td>
<td>34912000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Gastric decompression tube</td>
<td>A hollow tube that is connected to another tube (e.g., gastric feeding tube) to reduce the gastric pressure of patients with a gastrostomy.</td>
<td>70243000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Over tube</td>
<td>A tube that is used with an endoscope to secure a channel for catheters and other tubes in the gastrointestinal tract.</td>
<td>70244000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Biliary tract catheter</td>
<td>A balloon catheter used for bile duct drainage following biliary anastomosis.</td>
<td>70245000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Endoscopic dilation catheter</td>
<td>A catheter that is inserted to dilate a narrowed area by inflating the balloon under the endoscope. The device is intended for single-use.</td>
<td>70246000</td>
<td>II</td>
<td>5-2,6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheal suction catheter</td>
<td>A soft tube used to aspirate fluid and semisolid materials from the trachea. The device is intended for single-use.</td>
<td>10749000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Suction kit</td>
<td>A kit used for aspiration of secreta, consisting of sterilized gloves, aspiration catheter, and container for the aspirate. Some variants may not include gloves.</td>
<td>13846000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bronchial suction catheter</td>
<td>A flexible tube used for aspiration of fluid and semisolid materials from the pharynx, trachea, and bronchus.</td>
<td>31249000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bronchial drug infusion catheter</td>
<td>A flexible tube used for injection of drugs into the pharynx, trachea, and bronchus.</td>
<td>70248000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use tracheal tube cuff</td>
<td>A short-term use balloon-like cuff attached to around an endotracheal tube. This is placed below the vocal cords to seal the space between the tube and the tracheal wall during mechanical ventilation of the lungs.</td>
<td>14082012</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Medical Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Remarks</td>
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<tr>
<td>Ventilation tracheal tube</td>
<td>A balloon-like cuff attached to around a tracheal tube. This is placed below the vocal cords to seal the space between the tube and the tracheal wall during mechanical ventilation of the lungs.</td>
<td>14082022</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use ventilation tracheal tube</td>
<td>A cylindrical tube made of plastic or rubber inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, Cole type, may come in different internal/external diameters, lengths, or with or without a cuff.</td>
<td>14085012</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cole ventilation tracheal tube</td>
<td>A cylindrical tube inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, Cole type, may come in different internal/external diameters, lengths, or with or without a cuff.</td>
<td>14085022</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-Cole type ventilation tracheal tube</td>
<td>A cylindrical tube inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, non-Cole type, may come in different internal/external diameters, lengths, or with or without a cuff.</td>
<td>14085032</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use jet ventilation tracheal tube</td>
<td>A hollow, cylindrical device that is inserted into the trachea for jet (high-flow) ventilation. It is designed for short-term use. The device usually lacks a cuff so that the ventilated gas may be exhaled quickly.</td>
<td>17935002</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use laser-resistant ventilation tracheal tube</td>
<td>A hollow, cylindrical device that is inserted into the trachea to secure the airway patency or to administer anesthetics. It is intended for short-term use. The tube does not rupture or catch fire easily when it is exposed to a laser beam during head, throat, or neck surgery.</td>
<td>36064002</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reinforced ventilation tracheal tube</td>
<td>The hollow, cylindrical tube with a metal or plastic reinforcement on the internal surface, inserted into the trachea to secure the airway patency or to administer anesthetics.</td>
<td>14085042</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use nasopharyngeal tracheal tube</td>
<td>A rubber or plastic tube inserted into the pharynx via a nostril to secure the airway patency. The device may have a connector (diameter: 15 mm or 22 mm) at the tip for oxygen insufflation. The device is intended for single-use.</td>
<td>42422000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use oropharyngeal tracheal tube</td>
<td>A curved, metal or plastic tube inserted from the oral cavity to secure the airway patency in ventilation or aspiration. It is intended for short-term use. The device is useful to prevent airway obstruction by the tongue.</td>
<td>42424012</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Sterile suction tube and catheter</td>
<td>A device inserted into the trachea via the nasal or oral cavity to maintain the airway or for other purposes.</td>
<td>70249000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use esophageal/tracheal double-lumen tube</td>
<td>A double-lumen tube that can be used for artificial respiration or ventilation after securing the airway, regardless of whether it is inserted into the trachea or esophagus. The device has two cuffs (one closer to the distal end for the esophagus or trachea, and the other closer to the proximal end for ventilation).</td>
<td>70250002</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicability</td>
<td>Remarks</td>
<td></td>
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<tr>
<td>Short-term use oropharyngeal tube</td>
<td>A curved, metal, plastic, or rubber tube inserted via the oral cavity to secure the airway patency for ventilation or aspiration. It is intended for short-term use. The device is used to prevent airway obstruction by the tongue.</td>
<td>42424022</td>
<td>II</td>
<td>5⁻</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Saliva suction tube</td>
<td>A flexible tube connected to an aspirator and an aspirate container and used for aspiration of saliva and other substances from the oral cavity. The shape of the tip may be different from the usual suction tip.</td>
<td>70252000</td>
<td>II</td>
<td>5⁻</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Neonatal oropharyngeal suction catheter</td>
<td>A flexible tube used to suction amniotic fluids out of the neonatal oral cavity and the pharynx.</td>
<td>70253000</td>
<td>II</td>
<td>5⁻</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheobronchial introducer</td>
<td>A device used to insert a stent or catheter into the trachea or bronchus.</td>
<td>70254000</td>
<td>II</td>
<td>5⁻</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy cannula</td>
<td>A hollow, cylindrical device (cannula) used to secure the airway in the area of cricothyroid ligament in an emergency procedure. The device may contain a needle. The device is intended for single-use.</td>
<td>14089000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy tube cuff</td>
<td>An inflatable cuff attached around the tracheostomy tube. The cuff is used to fill the space between the tube and trachea for artificial ventilation in patients with subglottic stenosis.</td>
<td>14094000</td>
<td>II</td>
<td>5⁻</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract tracheotomy kit</td>
<td>A kit of surgical instruments and other accessories used when a tube is inserted or placed by puncturing the trachea or creating an opening in it to relieve upper airway obstruction and facilitate respiration. The kit may include a tube used to secure the airway patency after tracheostomy.</td>
<td>14099000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cricothyrotomy kit</td>
<td>A package kit, set, or tray containing instruments and tools required to cut or puncture the skin and cricothyroid membrane in an emergency procedure for upper airway obstruction.</td>
<td>15028000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy kit</td>
<td>A kit that contains a set of devices and other supplies (e.g., towels, gauze, a suction, swabs) to be used in tracheostomy.</td>
<td>35403000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use tracheostomy tube</td>
<td>A device inserted through an artificial opening into the trachea to secure patency after tracheostomy. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate prompt aspiration of secretions.</td>
<td>35404010</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy tube for adults</td>
<td>A device inserted through an artificial opening into the trachea to secure patency after tracheostomy. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate prompt aspiration of secretions. The device is usually made of plastic and may come with a plunger. The device also comes with/without a cuff, with/without an opening, and in various sizes to meet the need of each patient. The device is intended for single-use. The device is not intended for pediatric patients only.</td>
<td>35404020</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pediatric tracheostomy tube</td>
<td>A device inserted through an artificial opening into the trachea to secure patency after tracheostomy in infants. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate prompt aspiration of secretions. The device is usually made of plastic and may come with a plunger. The device also comes with/without a cuff, with/without an opening, and in various sizes to meet the need of each patient. The device is intended for single-use. The device is not intended for pediatric patients only.</td>
<td>35404030</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reinforced ventilation tracheostomy tube</td>
<td>A device inserted through an artificial opening into the larynx to secure the airway patency. The tube is reinforced with metal or plastic.</td>
<td>35404040</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Grade</td>
<td>Applicable</td>
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<tr>
<td>Tracheostomy tube inner tube</td>
<td>An inner cylinder that protects the inside of the tube from adhesion of secreta. The device is removable and can be washed outside the patient's body. The device is commonly there are types with or without holes in the inner cylinder to meet the need of each patient.</td>
<td>70255000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laryngectomy tube</td>
<td>A tube used to secure the airway patency in partial or total laryngectomy.</td>
<td>12292010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Post-laryngectomy tube</td>
<td>A tube used to secure the airway patency in patients who have undergone partial or total laryngectomy.</td>
<td>12292020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nasopharyngeal catheter</td>
<td>A flexible tube to be inserted into the nasopharyngeal cavity to suction or inject a drug.</td>
<td>16432002</td>
<td>II</td>
<td>5–②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bronchial balloon catheter</td>
<td>A flexible indwelling tube to be inserted into the bronchus. An inflatable balloon is attached to the distal end of the tube.</td>
<td>17827000</td>
<td>II</td>
<td>5–②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ventilation bronchial tube</td>
<td>A double-lumen cylindrical tube inserted into the trachea to administer anesthetics or used during pulmonary function tests. The device is equipped with two cuffs separately.</td>
<td>31329000</td>
<td>II</td>
<td>5–②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aerosol delivery tube</td>
<td>A flexible large-bore tube (usually diameter: 22 mm) to deliver aerosol usually connected to an oxygen mask, tracheal tube, humidifier, or nebulizer. The tube is usually supplied excessively long and cut into an appropriate length by healthcare professionals.</td>
<td>32202000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nasal cavity catheter</td>
<td>A semi-rigid or rigid, plastic or metal tubular surgical instrument inserted nasally into the nasal sinuses. This instrument is intended for injection/drainage of fluids or insertion of a catheter or surgical tools. The device is intended for single-use.</td>
<td>34903010</td>
<td>II</td>
<td>5-①,5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nasal cavity irrigation catheter</td>
<td>A catheter that is inserted through the nose for hemostasis with balloon, lavage, or draining.</td>
<td>34903020</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Oxygen delivery transtracheal catheter</td>
<td>A flexible tube to be inserted via the tracheal wall to supply oxygen when breathing through the nose or the mouth is impossible because of obstruction.</td>
<td>36231000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Oxygen supply-carbon dioxide collection transnasal catheter</td>
<td>A semi-rigid tube used to deliver oxygen or collect carbon dioxide (exhaled gas). Monitoring is done through prongs inserted separately into the nostrils. The device may have two cuffs (one for the esophagus and the other for the pharynx) when both cuffs are inflated. The pharyngeal cuff prevents air from contaminating the esophageal cuff.</td>
<td>36306000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use airway-esophageal obturator</td>
<td>A tube that is inserted into the esophagus from the oral cavity and has two lumina and two cuffs to support respiration. There is a hole for breathing between the pharyngeal and esophageal cuffs. When both cuffs are inflated, the pharyngeal cuff prevents air from contaminating the esophageal cuff.</td>
<td>42429000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Esophagus closing airway</td>
<td>A tube that secures the airway patency and performs artificial respiration or ventilation by occluding the esophagus with its cuff. The device may have two cuffs (one for the esophagus and the other for the pharynx).</td>
<td>70256000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Oropharynx tube</td>
<td>A tube used to secure ventilation (orally and transnasally) in the event of upper airway obstruction. Sterilized and non-sterilized products are included.</td>
<td>70257000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ventilation bronchial obstruction catheter</td>
<td>A bronchial catheter used to limit ventilation in one lung to administer anesthetics or perform pulmonary function tests. The device is intended for single-use.</td>
<td>70258000</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable mouthpiece connector</td>
<td>A hard, small device inserted into the patient's mouth and connected, usually through a tube, to a therapeutic or diagnostic ventilator. The mouthpiece easily fits the respiratory system only by holding it with his/her lips. It can be reusable after cleaned in an autoclave.</td>
<td>43467000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use mouthpiece connector</td>
<td>A hard, small device inserted into the patient's mouth and connected, usually through a tube, to a therapeutic or diagnostic ventilator. The mouthpiece easily fits the respiratory system only by holding it with his/her lips. It can be reusable after cleaned in an autoclave.</td>
<td>44545000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Item Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Subclass</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Body orifice obstruction balloon catheter</td>
<td>A balloon catheter used, for therapy or diagnosis, to fill an organ with a fluid or keep foreign bodies from entering the organ by partially occluding the organ. It is intended for short-term use.</td>
<td>70261000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nelaton catheter</td>
<td>A red, flexible rubber tube used for urinary catheterization.</td>
<td>10734000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urological catheter insertion/urine sampling kit</td>
<td>A kit that contains a sterilized urinary catheter and other accessories (e.g., urine collection bag) required for urinary catheterization or voiding.</td>
<td>14292000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intermittent urological catheter kit</td>
<td>A kit that contains a urinary catheter and other accessories that is used for urination from the bladder for sampling or other purposes.</td>
<td>16321000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Coude urological catheter</td>
<td>A flexible tube with a curved tip inserted in the bladder for injection or drainage of fluids for medical or surgical procedure. The tube is used to easily pass fluids to the bladder.</td>
<td>31981000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urological catheterization kit</td>
<td>A kit of materials necessary for urinary catheterization. The device is intended for single-use.</td>
<td>32030000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ureteral catheter</td>
<td>A flexible tube used to pass fluids to or from the ureter.</td>
<td>34926012</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use ureteral tube stent</td>
<td>A flexible tube inserted and placed in the ureter to drain pus and fluids or to perform lavage. It is intended for short-term use.</td>
<td>34926022</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intermittent urological catheter</td>
<td>A flexible tube inserted and placed in the bladder or ureter, for a relatively short term, for voiding, urine collection, or urodynamic testing.</td>
<td>36125000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urinary irrigation kit</td>
<td>A kit including a syringe(s) combined with other items that are used to cleanse the urethra and the bladder.</td>
<td>14301000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Continuous irrigation urological catheter</td>
<td>A flexible tube used for successive lavage of the bladder and its surroundings.</td>
<td>32331000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use self-retained urological catheter</td>
<td>A flexible tube placed in the bladder for a short term. The device has an inflatable balloon at the distal end. The device is usually used for voiding or hemostasis.</td>
<td>34917002</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Irrigation urological catheter</td>
<td>A flexible tube used for lavage of the bladder and its surroundings.</td>
<td>34930010</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Percutaneous irrigation urological catheter</td>
<td>A flexible tube used to cleanse the bladder and related structures percutaneously.</td>
<td>34930020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use nephrostomy catheter</td>
<td>A flexible tube percutaneously inserted into the renal pelvis to access the upper urinary tract. It is intended for short-term use.</td>
<td>10735002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use nephrostomy tube</td>
<td>A tube used for nephrostomy connecting the body surface near the pelvis and the kidney. It is intended for short-term use.</td>
<td>14224002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use stoma drainage urological catheter</td>
<td>A flexible tube inserted into a urinary stoma for voiding. It is intended for short-term use.</td>
<td>31074000</td>
<td>II</td>
<td>5-②,7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Male urethrographic urological catheter</td>
<td>A flexible tube used to inject a contrast medium into a male urethra for enhanced radiography.</td>
<td>32089000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicable</td>
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<tr>
<td>Short-term use suprapubic urological catheter</td>
<td>A flexible tube inserted into the urinary bladder of a male or female patient from an incision above the pubic bone (pubic arch) for voiding. It is intended for short-term use.</td>
<td>34924002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ureterolithotomy tube and catheter</td>
<td>A catheter inserted into the urinary tract to remove urinary stones. The device has a part such as a basket to capture stones.</td>
<td>70263000</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Olive-shaped tip catheter</td>
<td>A flexible tube with an olive-shaped tip used for dilatation of ureteral stricture.</td>
<td>10737000</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Filiform/filiform follower urological catheter</td>
<td>A flexible tube with a very thin or filamentous tip used to identify stenosis or sites with irregular shape or to widen the passage.</td>
<td>32022000</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use fibreoptic light ureteral catheter</td>
<td>A fiber catheter illuminator, etc. that is inserted into the urinary tract during lower abdominal or pelvic surgery to make the passage visible. This device consists of a bundle of optical fibers, etc. that radiates light along the entire length of the fibers and is</td>
<td>32035000</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Percutaneous urological catheter</td>
<td>A catheter used for percutaneous or endoscopic dilatation of the urinary tract.</td>
<td>70264000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ureteral locator</td>
<td>A tubular instrument made of vinyl or other materials with multiple valves. The device is inserted into the ureter to make palpation easier during laparotomy.</td>
<td>70265000</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urological extractor</td>
<td>A device inserted percutaneously or transurethrally into the urinary system for removal of foreign bodies such as intraureteral stones.</td>
<td>70266000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Central venous catheter repair tube</td>
<td>A tube used to repair or replace a damaged portion of the external part of a central venous catheter. A sleeve and an adhesive to ensure a tight bond may be including.</td>
<td>70268000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Arterial cannula</td>
<td>A semi-rigid tube to be inserted into an artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.</td>
<td>34893102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Femoral cannula</td>
<td>A semi-rigid or rigid tube to be inserted into a femoral vessel and used as a guide path for fluid. This device is for single-use.</td>
<td>34902102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Venous cannula</td>
<td>A semi-rigid or rigid tube to be inserted into a vein and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.</td>
<td>34905102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter for angiographic</td>
<td>A flexible tube to inject contrast media into an organ or peripheral vascular system for visualization of vascular structure of the targeted area.</td>
<td>10688102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Imaging pressure tube</td>
<td>A pressure-resistant tube used to inject contrast media into the heart, great vessels, or coronary arteries for cardiac or vascular radiography.</td>
<td>70269000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory arterial catheter</td>
<td>A flexible tube usually designed to pass through a non-central artery for injection or aspiration. The device is normally connected to a transducer or other apparatus for continuous measurement of arterial pressure.</td>
<td>10689002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory arterial microflow catheter</td>
<td>A flexible tube to be inserted into the circulatory system to exactly measure the blood flow and pressure of the artery in the non-central circulatory system.</td>
<td>10691002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory transducer-tip catheter</td>
<td>A catheter incorporating a built-in micro miniature pressure transducer at its distal end. When the catheter is inserted into the blood vessel of the non-central circulatory system.</td>
<td>15071002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Angiographic kit</td>
<td>A kit of devices and instruments for radiographic visualization of blood vessels. The kit excludes catheters inserted into a blood vessel or introducers.</td>
<td>16545002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Manometric balloon catheter</td>
<td>A flexible tube used to measure the pressure of each visceral organ. The catheter has a balloon at the distal end.</td>
<td>17745000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Guiding catheter for intravascular</td>
<td>A flexible tube used as a guide for a balloon catheter or guidewire during percutaneous vascular surgery.</td>
<td>17846102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pressure monitoring tube set</td>
<td>A set of tubes to be connected ex vivo (directly or via a valve) to a catheter transducer for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. The device has physical characteristics suitable for maintaining the blood pressure waveform and its precision.</td>
<td>35529000</td>
<td>II</td>
<td>2-1,2-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pressure monitoring damping device</td>
<td>A device for adjusting the damping coefficient during invasive blood pressure measurement.</td>
<td>70270000</td>
<td>II</td>
<td>2-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory intravascular catheter</td>
<td>A flexible tube inserted into a blood vessel for blood collection, blood pressure monitoring, or intravenous fluid administration.</td>
<td>40601000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Sialography catheter</td>
<td>A catheter inserted into a salivary gland for dilatation or contrast medium injection.</td>
<td>70278000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Embolization implant inserter</td>
<td>A long, thin surgical device used to advance an embolization implant such as an embolization coil through an appropriate catheter. When this catheter is placed in the target site of the artery or vein, the embolization implant is ready to be delivered (to be implanted). This device, also known as &quot;pusher,&quot; is removed before the implant is advanced. This device is for single-use.</td>
<td>43978000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter introducer</td>
<td>A sheath that facilitates percutaneous catheter placement in a vein or artery. The device may come with a puncture needle.</td>
<td>10678102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hemostasis valve</td>
<td>A valve used with a catheter or catheter introducer to stop the outflow of blood.</td>
<td>70279000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter for non-central circulatory embolectomy</td>
<td>A flexible tube designed to remove coagulation of blood and other substances that may lead to non-central vascular occlusion. The device is also used to remove occlusion of natural vessels, arterial access grafts, and access grafts for hemodialysis.</td>
<td>10714002</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intravenous catheterization kit</td>
<td>A kit of tools used to insert a catheter into a vein.</td>
<td>12161102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Introducer</td>
<td>A device used to help insertion of a needle into the skin for treatment or diagnosis.</td>
<td>12727010</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Introducer needle</td>
<td>A needle that is inserted into a patient's body for placement/manipulation of catheters and guidewires. The device may have a hemostasis valve.</td>
<td>12727020</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Balloon dilatation angioplasty catheter for non-central circulatory</td>
<td>A flexible tube that achieves dilatation of a stenotic non-central vessel by controlling balloon inflation. The device usually consists of a double-lumen catheter with a balloon at the distal end. The device may have a side hole for pressure recording or contrast medium.</td>
<td>17184002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Qty</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Snare catheter</td>
<td>A flexible tube or wire that is used to capture foreign bodies in a blood vessel or other ducts and used for retrieval or manipulation of these foreign bodies.</td>
<td>17927000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aspiration catheter</td>
<td>A catheter that is used to improve patency of the junction between the blood vessel and the manometer by being inserted into the vessel connected to the manometer. This device is intended for single-use.</td>
<td>34894000</td>
<td>II</td>
<td>2(\mathbb{1})</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Temporary use catheter guidewire</td>
<td>A device used temporarily to facilitate adjustment or transfer of a catheter in a blood vessel.</td>
<td>35094012</td>
<td>II</td>
<td>5(\mathbb{1}),6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-vascular guidewire</td>
<td>A guidewire (excluding probes) used in ducts other than blood vessels, such as urinary tracts, trachea/bronchi, bile duct, pancreatic duct, and gastrointestinal tract.</td>
<td>35094022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Peritoneal dialysis catheter guidewire</td>
<td>A guidewire used temporarily for correction of the position of a peritoneal dialysis catheter.</td>
<td>35094032</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter tip flow transducer</td>
<td>A catheter incorporating a built-in micro miniature transducer at its distal end. The miniature transducer detects and measures the blood flow rate. When the catheter is connected to a collecting can or bottle.</td>
<td>36040002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Vessel suturing lumen retention catheter</td>
<td>A catheter that is used for maintaining the inner diameter in angiorrhaphy.</td>
<td>70291000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Saphenous vein dilation system</td>
<td>A system used in a coronary artery bypass grafting to inject saline solution into a removed blood vessel. Injection of saline solution confirms that the blood vessel is intact. Inflation is performed by the surgeon.</td>
<td>70292000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Measure guide</td>
<td>A device used to check for a change in the distance between the double markers compared with the distance before the tip of the micro catheter with the markers was reshaped.</td>
<td>70298000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Autologous blood transfusion system tubing</td>
<td>A soft, hollow, cylindrical device usually used as an extension tube to pass blood between the bellows and the autotransfusion bag. This tube is made of a synthetic material. It can be used to maintain a closed circuit during recovery and reinfusion of blood.</td>
<td>42924000</td>
<td>II</td>
<td>2(\mathbb{2})</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-central circulatory intravascular occluding catheter</td>
<td>A flexible tube with a balloon (which may be detachable) at the tip used to block a non-central blood vessel.</td>
<td>32584002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bartholin's gland catheter</td>
<td>A flexible tube used to drain an inflamed Bartholin duct and Bartholin's gland.</td>
<td>10695000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pericardial drainage catheter</td>
<td>A flexible tube used to drain fluids or gases from a body cavity such as the pericardial cavity and pleural cavity.</td>
<td>10741102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Wound drain</td>
<td>A device, usually made of rubber or silicone, for removal of fluids or pus from a wound or infected area.</td>
<td>11305000</td>
<td>II</td>
<td>4(\mathbb{2})</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use multi-lumen catheter</td>
<td>A flexible, double-lumen (or multilumen) tube used for injection or drainage of fluids to or from inside the body (excluding those used for administration of drugs or in the central cardiovascular or central nervous system). The device is intended for single-use.</td>
<td>32330102</td>
<td>II</td>
<td>5(\mathbb{2},7)</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>General-purpose suction catheter</td>
<td>A flexible tube used to drain fluids and gases from a body orifice, surgical incision, or wound. When used with an aspiration unit, the device is usually be connected to a collecting can or bottle.</td>
<td>34923102</td>
<td>II</td>
<td>4(\mathbb{2},5),7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Cerebrospinal fluid reservoir</td>
<td>A system connecting with the ventricle in a closed system for drainage or collection of the cerebrospinal fluid to decrease intracranial pressure.</td>
<td>15974002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicability</td>
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</tr>
<tr>
<td>Shunt valve programmer</td>
<td>A device used to non-invasively (from outside the body) check or change the pressure setting of a pressure-adjustable shunt valve (for hydrocephalus). The valve pressure setting is controlled with an electrically generated magnetic power or dynamic power.</td>
<td>70305009</td>
<td>II</td>
<td>2-1 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DePezzer catheter</td>
<td>A catheter with a bulbous tip, used to drain fluid from the body cavity.</td>
<td>10709000</td>
<td>II</td>
<td>5-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter for eustachian</td>
<td>A tube used to drain fluid from the middle ear.</td>
<td>10718000</td>
<td>II</td>
<td>5-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal catheter</td>
<td>A flexible tube placed in the rectum for purposes such as irrigation.</td>
<td>10746000</td>
<td>II</td>
<td>5-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ileostomy rectal catheter</td>
<td>A flexible tube used as a template in continent ileostomy and used for postoperative drainage. In some cases, the tube is inserted by the patient on a regular basis to drain the contents of an ileal fistula. This device is for single-use.</td>
<td>40099000</td>
<td>II</td>
<td>5-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracic drainage tube</td>
<td>A straight or angled, single- or double-lumen tube used to drain secretions or irrigate the thoracic cavity after chest or heart surgery.</td>
<td>11308102</td>
<td>II</td>
<td>7 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drainage tube</td>
<td>A plastic or metal tube used to remove exudate or purulent material from a body cavity, wound, or infected area.</td>
<td>14191102</td>
<td>II</td>
<td>5-2,7 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sump drain</td>
<td>A double- or multi-lumen tube used to inject air via the smaller lumen and drain fluids from the larger lumen.</td>
<td>15270000</td>
<td>II</td>
<td>6 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocephalic shunt filter</td>
<td>A device made of a cellulose-like material and used with a shunt to drain fluid from the brain. This device prevents cellular materials or foreign substances from escaping from the shunt system.</td>
<td>15688000</td>
<td>II</td>
<td>3-1 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endolymphatic shunt</td>
<td>A tube to be inserted surgically into the inner ear to drain liquid from the membranous labyrinth.</td>
<td>16033000</td>
<td>II</td>
<td>7 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleuroperitoneal shunt</td>
<td>A tube made of plastic to be implanted surgically in the pleural cavity or the peritoneal cavity for drainage.</td>
<td>17218000</td>
<td>II</td>
<td>7 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Menstrual fluid collector</td>
<td>A cup-shaped container designed to be placed inside the vagina for collecting menstrual blood samples.</td>
<td>18132000</td>
<td>II</td>
<td>5-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound drainage kit</td>
<td>A package containing a plastic bag or bottle, trocar, and other tools used to drain fluids or pus from wounds.</td>
<td>35824102</td>
<td>II</td>
<td>4-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile intracorporeal indwelling drain tube and catheter</td>
<td>A tube and catheter placed in the body to drain unnecessary fluids after a surgery. It is also called a drain.</td>
<td>70306000</td>
<td>II</td>
<td>7 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound suction catheter</td>
<td>A catheter connected to an evacuating source such as portable aspirator and mainly used to aspirate exudate such as blood and lymph retained in a dead space after surgery.</td>
<td>70307000</td>
<td>II</td>
<td>4-2 applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irrigation catheter</td>
<td>A flexible tube used to inject or drain fluids (saline solution, for example) to or from body cavities excluding blood vessels (e.g., the stomach of a patient with bleeding esophageal varices).</td>
<td>10730000</td>
<td>II</td>
<td>5-2,7 applicable</td>
<td></td>
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</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Effect</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Short-term use umbrella catheter</td>
<td>A flexible tube where the diaphragm at the distal end opens when a catheter (e.g., an umbrella catheter for barium enema) is inserted into a body opening. It is for short-term use.</td>
<td>10760002</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Infusion catheter</td>
<td>A flexible tube used to inject solutions into the vein, subcutaneous tissue, or other tissues.</td>
<td>33172000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Peritoneal dialysis catheter hole button</td>
<td>A button-shaped instrument used for a short term to maintain an opening from the skin to the peritoneal cavity for insertion of a peritoneal dialysis catheter.</td>
<td>70309000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Peritoneal/pleural cavity catheterization kit</td>
<td>A toolkit used for percutaneous placement of a peritoneovenous shunt (in the peritoneal cavity) or pleuvenous shunt (in the pleural cavity).</td>
<td>70316000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Mushroom catheter</td>
<td>A flexible aspiration tube with a flared tip that is used to minimize the harm to the aspiration site.</td>
<td>10732000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Dental suction tube</td>
<td>A tubular dental instrument connected to an externally powered aspiration device (usually one dedicated for use in dentistry) and used for removal of fluids and cutting debris in the oral cavity.</td>
<td>70317000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>External shunt connector</td>
<td>A connector to an external shunt for hemodialysis. It is intended for short-term use. The device may have a side branch for injection of drugs such as anticoagulants.</td>
<td>70318000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Shunt thrombus suction set</td>
<td>A set used to suction a thrombus developing inside an arteriovenous shunt (external shunt) during procedures including hemodialysis.</td>
<td>70319000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use dialysis needle</td>
<td>An elongated, edged instrument used as a canal for the blood to go out and come in during hemodialysis. The device is intended for single-use.</td>
<td>12741002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Haemodialysis single needle with catheter</td>
<td>A flexible, double-lumen tube used with a single-needle. The device is used for hemodialysis via a single puncture.</td>
<td>34922000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Emergency blood access indwelling catheter repair tube</td>
<td>A tube used to repair or replace the damaged portion of the external part of a catheter for hemodialysis, etc. A sleeve and an adhesive to ensure a tight bond may be included.</td>
<td>70321000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Catheter needle</td>
<td>An elongated, edged, hollow device inserted into the patient’s body for placement/manipulation of catheters.</td>
<td>32337000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Adaptor for intravenous catheter</td>
<td>An instrument (usually small) used to connect an external apparatus for infusion or blood transfusion to a catheter. The device is intended for single-use.</td>
<td>44036000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cerebral introducer</td>
<td>A kit containing an instrument for facilitating insertion of a drainage catheter or endoscope into the body (catheter introducer), dilator, and endoscope cover. The device is intended for single-use. Not all of the components are included in some products.</td>
<td>70322000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Description</td>
<td>Code</td>
<td>Applicable Code(s)</td>
<td>Applicable</td>
<td></td>
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<tr>
<td>Catheter for radiography Uterine</td>
<td>18746000</td>
<td>Ⅱ 5②</td>
<td>applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Injection needle stylet</td>
<td>13836000</td>
<td>Ⅱ 1,6,7</td>
<td>applicable</td>
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<tr>
<td>Short-term use catheter balloon repair kit</td>
<td>31665002</td>
<td>Ⅱ 5②</td>
<td>applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ureteral catheter adaptor</td>
<td>31973000</td>
<td>Ⅱ 5②</td>
<td>applicable</td>
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<td></td>
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<tr>
<td>Angiography infusion stopcock</td>
<td>32172002</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>General-purpose blood flow circuit stopcock</td>
<td>35375012</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
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<td></td>
<td></td>
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<tr>
<td>Continuous flow catheter flush valve</td>
<td>35511000</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Introducer for catheter with hemostasis valve</td>
<td>36079000</td>
<td>Ⅱ 6</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Connector for angioplasty balloon dilatation catheter</td>
<td>36177000</td>
<td>Ⅱ 2②</td>
<td>applicable</td>
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<td></td>
<td></td>
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<tr>
<td>Obturator</td>
<td>70323102</td>
<td>Ⅱ 6</td>
<td>applicable</td>
<td></td>
<td></td>
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<tr>
<td>Balloon inflation gauge</td>
<td>70325000</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infusion pump stopcock</td>
<td>35375022</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
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<tr>
<td>Enteral nutrition pump gastrointestinal stopcock</td>
<td>35375032</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
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<td></td>
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<tr>
<td>Transfusion/catheter stopcock</td>
<td>35375042</td>
<td>Ⅱ 2②</td>
<td>applicable</td>
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<tr>
<td>Pressure monitoring stopcock</td>
<td>35375052</td>
<td>Ⅱ 2②</td>
<td>applicable</td>
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<td></td>
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<tr>
<td>Infusion/catheter accessory set</td>
<td>70326009</td>
<td>Ⅱ 2①</td>
<td>applicable</td>
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<tr>
<td>Device Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Remarks</td>
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<tr>
<td>Transfusion/catheter accessory set</td>
<td>70326002</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>A set of a transfusion set. It contains a blood purifier circuit, a cap for a catheter, a connector (either with or without an injection port), and a check valve.</td>
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<tr>
<td>Gastrointestinal catheter introducer</td>
<td>70329000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
<tr>
<td>An introducer used for percutaneous insertion of a catheter into the gastrointestinal tract or bile duct.</td>
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</tr>
<tr>
<td>Catheter positioner</td>
<td>70330000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
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<tr>
<td>A device used for insertion and placement of an indwelling catheter at an appropriate position in the ureter.</td>
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<tr>
<td>Intrauterine balloon</td>
<td>12155000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A balloon to be inserted into the uterus and inflated with air, gas, a sterile solution, etc. for suppression of bleeding from the inner wall in the uterus.</td>
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<tr>
<td>Single-use arthroscopy catheter</td>
<td>15983002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A flexible tube used in arthroscopy to examine the interior of a joint. This device is for single-use.</td>
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<tr>
<td>Intrauterine catheter</td>
<td>16431000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>A flexible tube used for detection and measurement of intrauterine and amniotic pressure.</td>
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</tr>
<tr>
<td>Rectosphincteric balloon</td>
<td>17781000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
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<tr>
<td>A hollow rubber balloon connected to a manometer to assess the function of the rectal sphincter. The balloon is inflated with air or liquid.</td>
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<tr>
<td>Suction/insufflation catheter</td>
<td>17795000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>A soft catheter used for aspirating or aerating air to the body cavity in order to remove or transfer substances in the cavity.</td>
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<tr>
<td>Carotid artery shunt</td>
<td>17797000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>A device used to prevent any interruption to the cerebral blood supply during surgery such as carotid endarterectomy.</td>
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<tr>
<td>Chorionic villi sampling catheter</td>
<td>18105000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>A soft catheter designed to collect in utero samples of filamentous process growing in the extraembryonic membrane (chorionic villi) in the outermost layer for genetic testing during the first trimester. Usually this device has a malleable, pre-shaped stylet which is inserted by ultrasonic induction. Sample suction is performed with an external syringe.</td>
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<tr>
<td>Manipulation/injection uterine catheter</td>
<td>33911010</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A rigid plastic or metal surgical instrument inserted into the uterus via the uterine cervix. The device is used to manipulate the position of the uterus, provide a route for other devices, and inject or drain drug solutions/liquids. The device may be inserted using a trocar. The device is intended for single-use.</td>
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<tr>
<td>Item Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Subclass</td>
<td>Applicability</td>
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<tr>
<td>Uterine manipulation set</td>
<td>A set that is used to secure visibility during laparoscopic surgery by manipulating the position of the uterus, and to inject or drain drug solutions/fluids in or from the uterus. The set consists of a balloon catheter, syringe, tube, and catheter, etc.</td>
<td>33911020</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Salpingography catheter</td>
<td>A flexible tube used to inject contrast medium into the uterine tube during radiography.</td>
<td>34157000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intrafallopian uterine catheter</td>
<td>A semi-rigid or rigid, plastic or metal tubular surgical instrument inserted using a hard, pointed trocar into the uterine tube via the uterine cervix and the corpus uteri. After the trocar is removed following the insertion procedure, the catheter is left in the uterine tube for subsequent procedures inside the tube or to guide other devices that are used to manipulate tissues. The device is intended for single-use.</td>
<td>34217000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Preterm membrane rupture catheter</td>
<td>A flexible tube to be inserted into the uterus to induce rupture of the membrane surrounding the fetus before the 37th week of pregnancy.</td>
<td>34218000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hemostatic catheter</td>
<td>A flexible tube to be inserted into the various sites of the body to stop blood flow. The device has a inflatable balloon and may be used with an endoscope.</td>
<td>34918000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Arthroscopy drainage catheter</td>
<td>A rigid or semi-rigid pipe inserted into a joint to inject or drain perfusion during or after arthroscopic surgery. The device may come with a trocar, obturator, or tube. The device is intended for single-use.</td>
<td>35620000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bronchial catheter</td>
<td>A semi-rigid or rigid plastic or metal tubular surgical device to be inserted into the tracheal lumen usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path.</td>
<td>35673000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Suprapubic catheter</td>
<td>A semi-rigid or rigid, plastic or metal tubular instrument inserted into the bladder from the suprapubic region. When the trocar with a hard tip (used for insertion of the catheter) is withdrawn, the catheter is left for voiding or guiding of another catheter or surgical instruments. The device is intended for single-use.</td>
<td>35789000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use general-purpose suction tip</td>
<td>A device attached to an aspirator used for adjustment/control of aspiration during a surgical procedure or treatment. This device is a general-purpose suction tip for single-use.</td>
<td>35917102</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use thoracic catheter</td>
<td>A semi-rigid or rigid tube to be inserted into the chest (the pleural space) to facilitate placement of a chest drain. It is for short-term use.</td>
<td>36247002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Percutaneous drainage peritoneal catheter</td>
<td>A flexible tube used for nonsurgical and transdermal drainage from abdominal tumors and for collecting fluids (infectious and noninfectious). This is mainly used for drainage of hepatic, subphrenic, subhepatic and pancreatic tumors or fluids.</td>
<td>37701000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Device Name</td>
<td>Description</td>
<td>National Registry Code</td>
<td>Category</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Reusable tracheostomy tube</td>
<td>A device inserted into the tracheostoma to secure the airway patency. The device is intended for patients who have undergone tracheal surgery (e.g., for respiratory stenosis) and designed to secure the airway patency, facilitate prompt aspiration of secretions, and prevent aspiration.</td>
<td>38792000</td>
<td>II</td>
<td>7</td>
<td>applicable N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable fibreoptic light ureteral catheter</td>
<td>An optical fiber catheter to be inserted into the urinary tract to confirm that the pathway is established. This device consists of a bundle of optical fibers that radiate light along the entire length of the fibers and is designed to be used in lower abdominal or pelvic surgery.</td>
<td>41605000</td>
<td>II</td>
<td>5-②</td>
<td>applicable N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable airway-esophageal obturator</td>
<td>A tube that is inserted into the esophagus from the oral cavity and has two lumina and two cuffs to support respiration. There is a hole for breathing between the pharyngeal and esophageal cuffs. When both cuffs are inflated, the pharyngeal cuff prevents air from flowing into the stomach, and the esophageal cuff prevents air from escaping from the esophagus.</td>
<td>42419000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable oropharyngeal tracheal tube</td>
<td>A curved plastic or metal tube to be inserted into the airway via the oral cavity to maintain airway patency during gas exchange or suction. This is useful to prevent the tongue from obstructing airflow. This device is reusable.</td>
<td>42423000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thoracic cavity drainage system with blood collection bag</td>
<td>A combination of a plastic device and a blood collection bag. The plastic device consists of at least one chamber connected to the suction tube. This device is connected to the chest drain to be used for removal of air and purulent secretions as well as for blood collection.</td>
<td>70332010</td>
<td>II</td>
<td>2-①,2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Orthopedic drain set with blood collection bag</td>
<td>A set that contains an aspiration tube and either a plastic tool, connected to the aspiration tube and having one or multiple chambers, or a blood collection bag. The device is used for removing fluids and blood.</td>
<td>70332020</td>
<td>II</td>
<td>2-①,2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Extension tube</td>
<td>A tube used to extend the lines for transfusion, blood transfusion, blood collection, fluid collection and administration of contrast media, etc. The device has connectors at both ends.</td>
<td>70333009</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transfusion/catheter extension tube</td>
<td>A tube used to extend a line used for blood transfusion, blood collection, fluid collection, contrast medium injection (excluding a pressure-resistant line), or infusion using a pump. The device has a connector at one or both ends. The device may also have a port for blood collection or injection.</td>
<td>12170012</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Auxiliary extension tube for blood tubing</td>
<td>A tube used to extend the main or additional line of blood tubing. This extension tube is a blood tubing component.</td>
<td>12170022</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intravenous tubing extension kit</td>
<td>A kit containing tubes and a connector(s) used to extend a standard venous line (IV) set. This kit is used when a tube included in an existing standard infusion set is too short to reach the infusion IV line or when the IV line is located too far away. This kit is for single-use.</td>
<td>12170032</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Enteral nutrition pump extension tube</td>
<td>An extension tube connected to a compatible enteral nutrition set, used to deliver enteral nutrients from a pump. The device’s connector is designed to be incompatible with an infusion line.</td>
<td>12170042</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion pump extension tube</td>
<td>A tube used to extend a line connected to an infusion pump. The device has a connector at one or both ends. The device may have an injection port.</td>
<td>12170052</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood transfusion set extension tube</td>
<td>A tube used to extend a line such as a blood transfusion line or the line of a blood collection set. The device has a connector at one or both ends. The device may have an injection port.</td>
<td>12170062</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Needle-less contrast medium infusion set extension tube</td>
<td>A tube used to extend a line of needle-free contrast media infusion set. The device has a connector at one or both ends. The device may have an injection port.</td>
<td>12170072</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Protective overtube</td>
<td>A flexible tube used to prevent injury by devices inserted into the body such as sensors, guidewires, and indwelling cannulas. The device is intended for single-use.</td>
<td>70334000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ovarian cyst evacuation set</td>
<td>A set of metal pipes and needles used in aspiration/drainage of contents of ovarian cysts or in subsequent lavage. The needle included in the set may have a balloon attached. Not all of the components are included in some products.</td>
<td>70335000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Product Description</td>
<td>Details</td>
<td>Code</td>
<td>Class</td>
<td>Application Code</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Reusable bronchial cannula</td>
<td>A semi-rigid or rigid plastic or metal tubular surgical device to be inserted into the tracheal lumen by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path for suction.</td>
<td>70338000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Lacrimal fluid/passage silicone tube</td>
<td>A tube made of silicone or polyurethane, etc. used to treat epiphora induced by occlusion of the lacrimal punctum, lacrimal canaliculus, or nasolacrimal duct, etc. This tube is inserted or placed in the lacrimal canaliculus, etc. to dilate the lacrimal passage. It usually comes with a device(s) used for insertion of the tube.</td>
<td>70337102</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Tubal patency catheter</td>
<td>A catheter inserted into the uterus for tubal patency test.</td>
<td>70340000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Dialysis priming /fluid replacement set</td>
<td>A single-use, sterilized set used for flushing of the blood tubing, fluid replacement, or drainage. In using, the set may be integrated with a blood tubing. One end is connected to the drug solution or drain while the other is connected to the tubing.</td>
<td>70341000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Non-sterile bronchial tube</td>
<td>A cylindrical tube with two cavities to be inserted into the trachea for anesthetic administration or pulmonary function testing. It has tracheal and bronchial cuffs, which regulate ventilation to one of the two lungs, when necessary. It is not sterile.</td>
<td>70342000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Artificial insemination catheter</td>
<td>A flexible tube used in artificial insemination, i.e., delivery of sperm or fertilized ovum into the uterus. The device is intended for single-use.</td>
<td>70345010</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Embryo transfer catheter</td>
<td>A flexible tube used in in vitro fertilization or embryo transfer. The device is intended for single-use.</td>
<td>70345020</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Electromagnetic thermotherapy set</td>
<td>A set that contains a catheter used as protective material during electromagnetic hyperthermia, needle, and tube, etc.</td>
<td>70347000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Urinary tract pressure measurement catheter</td>
<td>A device connected to a pressure gauge and inserted via the urethral orifice to measure the pressure inside the ureter, bladder, or urethra.</td>
<td>70348000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Female urethral imaging urological catheter</td>
<td>A tube through which contrast media is injected or a metal chain is inserted into the female urethra for radiography.</td>
<td>70349000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Device Description</td>
<td>A device used during brachytherapy to place the radioactive seed or source within a body cavity. It is designed to fix a catheter in place.</td>
<td>38437000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Sealed small radiation source catheter</td>
<td>A catheter inserted through the uterus into the uterine tube to recover tubal patency. The balloon attached to the catheter tip dilates the uterine tube under salpingoscopy. By progressing into the uterine tube, the lumen of uterine tube can be observed and the...</td>
<td>70350000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Salpingoplasty catheter</td>
<td>A balloon attached to the catheter tip dilates the uterine tube under salpingoscopy. By progressing into the uterine tube, the lumen of uterine tube can be observed and the...</td>
<td>70351000</td>
<td>II</td>
<td>5-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Trocar application cuff</td>
<td>A flexible rubber cuff that is placed inside the incision to protect the tissue when an instrument such as trocar and forceps, or a hand is inserted into the body cavity.</td>
<td>70357000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood component separation bag</td>
<td>A plastic bag used to collect, isolate, preserve, treat, transport, or infuse blood or blood components. The bag is blood preservative-free.</td>
<td>70359000</td>
<td>II</td>
<td>2-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Frozen bag</td>
<td>A plastic bag used to collect, isolate, preserve, discard, transport, or infuse blood or blood components, including those which can be frozen. The bag is blood preservative-free.</td>
<td>70360000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood donor set</td>
<td>A set of flexible plastic bag(s) (at least one soft bag), a tube, and a hollow needle attached to the tube (to be inserted into the donor's vein). After the blood is collected, the blood is kept in one bag, or separated blood components (for example, red blood cell, plasma) are kept in multiple bags. Usually collected blood and blood components are analyzed, stored, or used as needed. The device is intended for single-use.</td>
<td>10426000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Exchange blood transfusion set</td>
<td>A vascular injection set used to withdraw blood from a sick neonate/infant and simultaneously replace it with a donor's blood or plasma. Usually the set includes a needle, catheter, tube, flow regulator, drip chamber, injection filter, stopcock for an intravenous infusion set, injection tube, connectors, side tube with a cap that can be used as an injection port, and spike to connect the tube to a container such as an intravenous infusion bag or other infusion.</td>
<td>35405000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood transfusion set</td>
<td>A vascular injection set used to inject blood from a container into the blood vessel of a patient via a needle or catheter. This set may include a needle, catheter, tube, flow regulator, drip chamber, injection filter, stopcock for an intravenous infusion set, injection tube, connectors, side tube with a cap that can be used as an injection port, and spike to connect the tube to a container such as an intravenous infusion bag or other infusion.</td>
<td>38569000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Arterial blood sampling kit</td>
<td>A kit containing a syringe, needle, and plug, etc. for sampling of arterial blood. The device is usually used for blood gas analysis.</td>
<td>31360000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood collection kit with blood sampling port</td>
<td>A tube equipped with a reservoir and blood sampling port for collection of blood in a closed circuit. The device is connected to another device (e.g., catheter) by a connector, and the blood is aspirated via the blood sampling port on manipulation of the reservoir. Devices...</td>
<td>70360000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Fetal scalp blood sampling kit</td>
<td>A kit containing items used to collect blood from the fetal scalp transvaginally at delivery. Usually, the kit has a device used to puncture the scalp for blood sampling, such as syringes, needles, plastic cones and thin blood collection tubes as well as swabs and antiseptic solutions. This kit is for single use.</td>
<td>16873000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-pack blood donor set</td>
<td>A set of a flexible plastic bag(s) (one soft bag), a tube, and a hollow needle attached to the tube (to be inserted into the donor’s vein). Collected blood is analyzed, stored, or used as needed. The device is intended for single-use.</td>
<td>44033000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Double-pack blood donor set</strong></td>
<td>A set of flexible plastic bags (two soft bags), tube, and hollow needle attached to the tube (to be inserted into the donor's vein). After the device collected the blood, blood components (e.g., red blood cell, plasma) are isolated and kept in separate bags. Usually</td>
<td>44034000</td>
<td>II</td>
<td>2②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Triple-pack blood donor set</strong></td>
<td>A set of flexible plastic bags (three soft bags), tube, and hollow needle attached to the tube (to be inserted into the donor's vein). After the device collected the blood, blood components (e.g., red blood cell, plasma) are isolated and kept in separate bags. Collected blood and blood components are analyzed, stored, or used as needed. The device is</td>
<td>44037000</td>
<td>II</td>
<td>2②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Blood bag negative pressure blood sampling device</strong></td>
<td>A device used with a blood bag to support vacuum blood sampling.</td>
<td>70361000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Specific gravity test kit</strong></td>
<td>A set of sterilized items including a tube and hollow needle attached to the tube (to be inserted into the donor's vein). It may come as a tube integrated with the needle. Usually, blood drawn into the tube is used to determine specific gravity, blood type, or parameters</td>
<td>70363000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Open blood collecting tube</strong></td>
<td>A tube used during blood collection. The tube ends are open, and the blood coming through an inserted tube is filled in this device. Some products can be sealed with a cap or plug. The device is intended for single-use.</td>
<td>34590000</td>
<td>II</td>
<td>2②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Testing evacuated sealed blood collecting tube</strong></td>
<td>A tube used in the laboratory together with a blood collection tube adapter and blood collection needle. It is partially evacuated and sealed when provided. The blood comes into the tube because of vacuum. The device allows pretreatment of blood with various chemicals depending on the purpose without transfer of blood to other containers.</td>
<td>35414009</td>
<td>II</td>
<td>2②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Evacuated sealed blood collecting tube</strong></td>
<td>A tube used in blood collection together with a blood collection tube adapter and blood collection needle. It is partially evacuated and sealed when provided. The blood comes into the tube because of vacuum. The device allows pretreatment of blood with various</td>
<td>35414000</td>
<td>II</td>
<td>2②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Blood filter</strong></td>
<td>A filter inserted inside a blood transfusion line to remove impurities from blood that enters the patient's body. The device may also be used to capture bubbles in arterial blood.</td>
<td>36071000</td>
<td>II</td>
<td>3①</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Blood/solution warmer</strong></td>
<td>An apparatus used to warm preserved blood, blood products, or drugs before administration. Usually the device warms the bag directly or in a special set or a plastic tube (e.g., with a heating coil for blood/drug solution). The device does not include single-use accessories (e.g., tubes)</td>
<td>10447000</td>
<td>II</td>
<td>3①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>High-flow blood/solution warmer</strong></td>
<td>An apparatus used to warm blood or other fluids for rapid infusion when severe bleeding occurs during surgery or in the event of burns/scalds or trauma. The maximum flow rate exceeds 1 liter/min in some products. The heating medium may be water or a heat-transfer surface (that transmits heat to the single-use set used in a specific type of heater). The device does not have a function of injecting fluids</td>
<td>38446000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Arteriotomy kit</strong></td>
<td>A kit consisting of the tools needed for blood collection, such as test tubes, a rack(s), needles, bandages, gauze pads and a needle container.</td>
<td>18926000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Portable blood sampling pump</strong></td>
<td>A device used to continuously perform controlled blood sampling for a predefined period (usually for 24 hours). This device is attached to the patient's body, and the patient has to carry the device for the predefined period. After use, the device is returned to the hospital</td>
<td>36997000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Blood/solution warming coil</strong></td>
<td>A plastic tube used with devices that warm preserved blood, blood products, or drugs (fluid warmer for blood and therapeutic solution, fast-flow fluid warmer-pump, and fast-flow fluid warmer for blood and therapeutic solution) before injection. The device may</td>
<td>70368000</td>
<td>II</td>
<td>3①</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Infusion start kit</strong></td>
<td>A package that includes a needle, tube, and other instruments used to establish venous access for intravenous infusion.</td>
<td>33963000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Intravenous administration set with noncoring needle</strong></td>
<td>A set of tools used for intravenous fluid administration. The device includes a tube, clamp, and needle (solid with a side hole). The device is used in an implanted injection/infusion port</td>
<td>17701000</td>
<td>II</td>
<td>2.5①</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td><strong>Intravenous administration set for scalp vein</strong></td>
<td>A set of devices used to administer a solution intravenously. The set includes tubes, clamps, and needles and needle holders appropriate for scalp intravenous injection. The set is usually used for pediatric patients (in particular for infants)</td>
<td>17825000</td>
<td>II</td>
<td>2.6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Grade</td>
<td>Applicable</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td>Infusion pump infusion administration set</td>
<td>An infusion set specifically used for transfer of the infusion solution from the pump to the infusion site.</td>
<td>35833000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Insulin pump infusion administration set</td>
<td>An infusion set specifically designed for injection of drugs from an insulin pump.</td>
<td>35838000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion administration set controller</td>
<td>A dedicated infusion set used to deliver an infusion solution from the infusion controller to the infusion site. Usually it consists of tubes, a clamp(s), a protective rack(s), and placebo group, etc.</td>
<td>36244000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intravenous administration set with heat exchange function</td>
<td>A type of set for intravenous administration. It is designed to directly warm an infusion solution to be administered.</td>
<td>41609000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Gravity pour/infusion pump infusion administration set</td>
<td>An infusion set used to inject infusion solution into the infusion site of the patient or recipient. The device transfers solution either by gravity (without an active device) or with an active device such as an infusion pump.</td>
<td>70371000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion administration set with venous pressure measurement function</td>
<td>An infusion set that is used to inject infusion solution into the infusion site of the patient or recipient and is also capable of measuring venous pressure.</td>
<td>70372000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Contrast media infusion administration set</td>
<td>An infusion set used to inject contrast media into the infusion site of the patient or recipient. The device transfers contrast media either by gravity (without an active device) or with an active device such as infusion pump. The device may come with a filter, three-way stopcock, and connector for mixed injection, etc.</td>
<td>70373000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Contrast media infusion administration set without needle</td>
<td>An infusion set that contains no puncture needle and is used to transfer contrast medium from its bottle to the syringe, for catheter-based angiography. The device may come with a three way stopcock and burette, etc.</td>
<td>70374000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Enteral nutrition pump infusion set</td>
<td>An enteral nutrition set specifically for delivery of enteral nutrients from a pump. The connector of the device is designed to be incompatible with an infusion line.</td>
<td>70376000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Syringe filter</td>
<td>An instrument connected to a syringe for removal of foreign bodies from the injection solution.</td>
<td>15283000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Intravenous line filter</strong></td>
<td>An instrument used with an infusion line to remove microorganisms and other foreign bodies from the infusion. The device may also be used to remove air.</td>
<td>35072000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use winged needle for general veins</strong></td>
<td>A very thin, edged instrument commonly used for venipuncture. The device is intended for single-use.</td>
<td>70378000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use winged scalp vein needle</strong></td>
<td>A very thin, edged instrument used in a scalp vein or other small veins (especially for pediatric patients). The device is intended for single-use.</td>
<td>35211002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use blood preservation in-line backflow check valve</strong></td>
<td>A device used to prevent reflux of gas or liquid in a medical tube or pipeline. This is used for blood preservation. This device is for single-use.</td>
<td>34099002</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable active device connected backflow check valve</strong></td>
<td>A device used to prevent reflux of gas or liquid in a medical tube or pipeline. This device is connected to the active device, and is reusable.</td>
<td>42548002</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Reusable intravenous infusion set</strong></td>
<td>A set containing tubes, a clamp(s), needles, etc. which are used to infuse the solution for intravenous administration. This set is not sterilized and reusable.</td>
<td>70382000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Continuous flow flush device</strong></td>
<td>A device with a channel that allows a constant infusion rate to be maintained in order to assist arterial pressure measurement and retain patency. A fixing valve of the device has a manual mechanism that enables flushing of the line at a rate about the same as free flow.</td>
<td>70383000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Prefilled syringe with needles</strong></td>
<td>A single-use glass or plastic syringe with a needle, used to administer drug. Usually, the syringe is designed to contain single dose of drugs.</td>
<td>70390000</td>
<td>II</td>
<td>2,6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Pen-type medication injector</strong></td>
<td>A manually operated pen-type device used for intramuscular or subcutaneous injection of drugs (excluding insulin) into the human body. The device is reusable (mostly pen-type), and each injection requires a new replaceable needle tip to be attached. The structure of the injector is fixed and consistent.</td>
<td>70391000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use ophthalmic medication injector</strong></td>
<td>A device for infusion of a drug solution (e.g., a viscoelastic substance) into the eye in ophthalmic surgery. The device is usually made of glass or plastic and consists of a container and plunger. The device is intended for single-use.</td>
<td>70393000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable medication/vaccine injector</strong></td>
<td>A device used for intramuscular (IM) or subcutaneous injection of drugs/vaccines into the human body. The device is usually reusable and comes in varying forms depending on the type of medication. It is either manually operated or powered (e.g., by spring compressed or gas-driven).</td>
<td>12504002</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable mechanically-powered needleless medication/vaccine injector</strong></td>
<td>A hand-held mechanical device (spring-type) used for transdermal injection of drugs (particularly, of a local anesthetic) or vaccines into the human body. This is needleless and reusable, and structured in various ways according to use. Usually, it is a gun-type plunger-driven syringe with one or more holes on the syringe from which a drug or vaccine is extruded under high pressure. A drug or a vaccine to be injected is loaded into a syringe from a separate vial.</td>
<td>18069000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable gas-powered needleless medication/vaccine injector</strong></td>
<td>A hand-held gas-driven device used for transdermal injection of drugs (particularly, of a local anesthetic) or vaccines into the human body. This is needleless and reusable, and structured in various ways according to use. Usually, it is a gun-type plunger-driven syringe with one or more holes on the syringe from which a drug or a vaccine is extruded.</td>
<td>42949000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Designation</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Risk Level</td>
<td>Availability</td>
<td>Needles or Needles Material</td>
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<tr>
<td>Non-intravenous infusion pump</td>
<td>A device used for injection of drugs and solutions into the patient's body (other than blood vessels) in an accurate and constant manner. The device may require a syringe for use. The device is not used for subcutaneous injection of insulin or vaccines or administration of breast reconstruction, and to improve the aesthetic appearance of other body parts. Available with syringes.</td>
<td>70394000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use dye injector</td>
<td>An injector for promoting pigmentation by skin penetration. It is used by a physician to cover scars and burns, to make artificial eyebrows, to make a nipple appear natural after breast reconstruction, and to improve the aesthetic appearance of other body parts. This device requires a syringe for use.</td>
<td>17660002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use indicator injector</td>
<td>A syringe-like device used to accurately perform bolus injection of an indicator (e.g., cold saline solution) into the bloodstream. The device is usually used for delivery of the indicator to the heart, for evaluation of blood flow through the heart. The device's variants are used with a densitometer or thermal dilution cardiac output flowmeter for cardiac catheterization.</td>
<td>31736002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Obstetric anaesthesia kit</td>
<td>A kit containing a set of items including injection needles, catheters, syringes, sterilized gauze, skin disinfectants, local anesthetics which are used for local block during labor and delivery.</td>
<td>33595000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Brachial plexus anaesthesia kit</td>
<td>A kit containing a set of items including injection needles, syringes, sterilized gauze, and skin disinfectants used for upper extremity nerve block (supraclavicular nerve, intercostal nerve, subclavian nerve, axillary nerve, brachial plexus). Some types are used for local block during paracervical block, uterosacral block, and genital block.</td>
<td>34840000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Caudal anesthesia kit</td>
<td>A kit containing a set of items used for injecting local anesthetics into the sacrum and the sacral canal.</td>
<td>34841000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Epidural anaesthesia kit</td>
<td>A kit containing a set of items necessary for injecting anesthetics into the epidural space.</td>
<td>34842002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Glossopharyngeal anaesthesia kit</td>
<td>A kit containing a set of items necessary for administering anesthetics to the tongue and the pharynx.</td>
<td>34843000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Pudendal anaesthesia kit</td>
<td>A kit containing a set of items necessary for injecting anesthetics into the external genitalia.</td>
<td>34844000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Saddle block anaesthesia kit</td>
<td>A kit containing a set of items necessary for injecting anesthetics into the dural sac in the areas corresponding to the buttocks, the perineum, and the medial thigh.</td>
<td>35888000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Laryngotracheal anaesthesia kit</td>
<td>A kit containing a set of items necessary for injecting anesthetics into the upper trachea and the sublingual structure.</td>
<td>35905000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Paracervical anaesthesia kit</td>
<td>A kit of items including antiseptic solutions, injection needles, needle guides, syringes, and other accessories used with anesthetics. This set is used for local block (e.g., paracervical block, uterosacral block, genital block) in labor, delivery, or both of these events.</td>
<td>42325000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Blood/body fluid transfusion/enteral nutrition infusion set</td>
<td>A device that is connected to a catheter inserted into the stomach or intestine, for administration of enteral nutrition. The device can be used for transfusion of blood and other bodily fluids.</td>
<td>70398000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Implantable port drug injection device</td>
<td>A device consisting of a needle (for injection of drugs into an implanted port), tube, etc.</td>
<td>70401000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Powered syringe for dental anaesthesia</td>
<td>An electric injector (with a cartridge filled with anesthetic solution and a sterilized needle) for dental anesthesia. The anesthetic is injected on operating the switch.</td>
<td>70402000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Description</td>
<td>Code</td>
<td>Subcategory</td>
<td>Type</td>
<td>Applicable Uses</td>
<td></td>
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<tr>
<td>Single-use manually-operated barium enema contrast medium delivery/evacuation kit</td>
<td>70403000</td>
<td>II</td>
<td>5-2,11</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion connecting tube</td>
<td>70404000</td>
<td>II</td>
<td>2-2</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use hemostatic clip applier</td>
<td>36126000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Umbilical tape</td>
<td>13983000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use suture needle</td>
<td>70417002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use automatic suturing device</td>
<td>15065002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use arthroscopic suture unit</td>
<td>17735002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-absorbable gastrointestinal anastomosis coupler</td>
<td>18135002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
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<tr>
<td>Vascular anastomosis coupler</td>
<td>18137002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical stapler</td>
<td>32369009</td>
<td>II</td>
<td>6,7,9</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>Single-use surgical stapler</td>
<td>32389002</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Single-use wire/ligature passer</td>
<td>32864002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantable hemostatic clip (exclude reusable use)</td>
<td>34050000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
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</tr>
<tr>
<td>Item Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Subcategory</td>
<td>Applicable</td>
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<tr>
<td>Surgical vascular clamp (exclude reusable use)</td>
<td>A surgical instrument used to temporarily stop blood flow in an anastomosed vessel. The vascular</td>
<td>35596000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<tr>
<td></td>
<td>clamp usually includes peripheral vessel clamps and iliac clamps. The reusable device is excluded.</td>
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<tr>
<td>Removable skin staple (exclude reusable and absorbable use)</td>
<td>A metal (e.g., stainless steel or titanium) device with a pistol-like applicator to close or</td>
<td>35884002</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
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<td></td>
<td>approximate a wound or edges of an incision. The edges of a wound or incision are</td>
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<td>approximated by the applicator, and staples are applied to hold the edges together. Staples</td>
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<td>are removed when the wound or incision is cured. Reusable and absorbable staples are</td>
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<tr>
<td>Single-use suture passer</td>
<td>A surgical instrument used to pass sutures and suture needles through body tissue. Usually it is</td>
<td>37839002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<td>a flexible or firm rod with a handle and a hook, catch, or clasp to pass the material through</td>
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<td>tissue. The device may have a ring-shaped handle and a linear or curved blade. The device is</td>
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<td></td>
<td>intended for single-use.</td>
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<tr>
<td>Single-use staple remover</td>
<td>A metal or plastic surgical instrument used to remove staples from a surgical wound or incision</td>
<td>16787002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
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<td></td>
<td>that no longer requires stapling to stay closed. The device is intended for single-use.</td>
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<tr>
<td>Umbilical occlusion clip</td>
<td>A device used to ligate/close the umbilical blood vessels of a neonate. It is intended for</td>
<td>32192000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<td>single-use and discarded after healing.</td>
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<tr>
<td>Single-use surgical umbilical clamp</td>
<td>A surgical instrument used to compress (constrict) the umbilical cord after childbirth. The device</td>
<td>43998000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
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<td>is used before transection or ligation of the umbilical cord to achieve hemostasis</td>
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<tr>
<td>Surgical aortic clamp (exclude reusable use)</td>
<td>A surgical instrument used to compress an aorta temporarily in an atraumatic manner. The device</td>
<td>34947000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<tr>
<td></td>
<td>may use an inserter made of varying materials. It includes anastomosis clamps for</td>
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<tr>
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<td>aorta and clamps for aortic aneurysm. The reusable device is excluded.</td>
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<tr>
<td>General-purpose artery clamp (exclude reusable use)</td>
<td>A surgical instrument used to compress an artery temporarily in an atraumatic manner. The device</td>
<td>34948000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td></td>
<td>is excluded.</td>
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<tr>
<td>Surgical intestinal clamp (exclude reusable use)</td>
<td>A surgical instrument used to hold, join, compress, or support the intestine in an</td>
<td>34953000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td></td>
<td>atraumatic manner during gastrointestinal surgery. The reusable device is excluded.</td>
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</tr>
<tr>
<td>Surgical rectal clamp</td>
<td>A surgical instrument used to hold, join, compress, or support the rectum, rectal valve, or</td>
<td>35542002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
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<td></td>
<td>anal canal in an atraumatic manner. The device is intended for single-use.</td>
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<tr>
<td>Surgical carotid clamp</td>
<td>A surgical instrument used to compress the carotid artery. The device is intended for</td>
<td>35593002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td></td>
<td>single-use.</td>
<td></td>
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<tr>
<td>Endoscopic esophageal varices ligation therapy ligator set</td>
<td>A set used together with an endoscope for ligation of esophageal varices (in endoscopic</td>
<td>70420002</td>
<td>II</td>
<td>5,②</td>
<td>applicable</td>
<td>–</td>
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<tr>
<td></td>
<td>variceal ligation). The device consists of a transparent hood to be attached to the endoscopic</td>
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<td>tip and an O-ring-shaped band made of rubber or elastomer used to ligate a varix.</td>
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</tr>
<tr>
<td>Ligating tape</td>
<td>A band-shaped or tubular thread or tape for temporary ligation of a blood vessel or other tissues.</td>
<td>70423000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
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<td></td>
<td>A needle may be attached to it.</td>
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</tr>
<tr>
<td>Reusable scalp clip</td>
<td>A sterilized surgical instrument with two blades joined at the middle or consisting of one α-</td>
<td>34959002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>shaped part. It is used to achieve hemostasis during scalp surgery. (Excluding a non-</td>
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<td></td>
<td>sterilized instrument. ) This instrument is reusable.</td>
<td></td>
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</tr>
<tr>
<td>Single-use skin clip</td>
<td>A surgical instrument with two blades joined at the middle or consisting of one α-shaped part.</td>
<td>34960000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>The device is used to pull skin incision edges closer during a procedure or to fix an object (e.g.</td>
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<tr>
<td></td>
<td>electrode) to the skin. The device is intended for single-use.</td>
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</tr>
<tr>
<td>Endoscopic loop ligator</td>
<td>A device used with a special endoscope during endoscopic therapy. It is used to ligate a polyp</td>
<td>36176000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>with a loop of wire to achieve hemostasis or induce necrosis and sloughing. The device comes</td>
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<tr>
<td></td>
<td>with an insertion sheath, a loop of wire attached to the sheath tip, a control.</td>
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<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicability</td>
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<tr>
<td>Surgical clip</td>
<td>A surgical instrument having two blades joined at the middle or consisting of one α-shaped part. It temporarily holds or fixates another instrument, device, or tissue.</td>
<td>37406000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use scalp clip</td>
<td>A surgical instrument having two blades joined at the middle or consisting of one α-shaped part. The device is used to achieve hemostasis during scalp surgery. The device is intended for single-use.</td>
<td>37458000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use surgical punch</td>
<td>A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc. The device is intended for single-use.</td>
<td>35285012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Surgical aortic punch</td>
<td>A surgical instrument used to resect tissues and create a hole in the aorta for anastomosis during vascular surgery. The device is intended for single-use.</td>
<td>35285022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use urinary incontinence sutureing needle</td>
<td>A device for elevating the female bladder neck to treat urinary incontinence. This device is for single-use.</td>
<td>70430002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urinary incontinence prevention prosthesis</td>
<td>A device for elevating the bladder neck to prevent urinary incontinence.</td>
<td>70431000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transparent adhesive dressing</td>
<td>A transparent film (made of polyurethane, etc.) having an adhesive area (e.g., margin) used to cover and protect a wound yielding a small amount of exudate.</td>
<td>17428000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-adhesive dressing</td>
<td>A gauze or pad-like dressing coated with or soaked in an emulsion of silicone or white petrolatum for protection of wounds without adhesion.</td>
<td>11325000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Local control hydrogel dressing</td>
<td>A local wound dressing made of hydrophilic polymer for absorption of exudate, reduced blood/body fluid loss, and protection of wounds from scratching, abrasion, dryness, and contamination.</td>
<td>34082002</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Local control saline solution-containing dressing</td>
<td>A local wound dressing containing hypertonic saline solution used for accelerating biological cleaning of wounds and autolytic debridement.</td>
<td>37298002</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Local control hydrophilic gel-forming dressing</td>
<td>A local wound dressing, usually appearing like a sheet or ribbon, made of hydrophilic fiber, chitin, or alginate (salt and acid), etc. that accelerates autolytic debridement by absorbing exudate and maintaining wet microenvironment.</td>
<td>43186002</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Burn kit</td>
<td>A package of required items used in combination for treatment of first- or second-degree burns, including dressings and antibiotics.</td>
<td>10516000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Local control foam dressing</td>
<td>A local wound dressing comprising a superabsorbent pad made of hydrophilic foam for covering wounds with a large amount of exudate.</td>
<td>11323002</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Surgical packing</td>
<td>A cylindrical gauze. The gauze comes in various widths and is soaked with vaseline, povidone iodine, etc. and is used for filling surgical incisions.</td>
<td>13886000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
<td></td>
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<tr>
<td>Item Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Quantity</td>
<td>Applicable</td>
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<tr>
<td>Wound protecting ring</td>
<td>A round, plastic cover with a hole at its center. The dressing is affixed to the skin around the surgical wound or placed over the wound for protection. The dressing may also be used to hold a surgical drape.</td>
<td>44273000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use first aid emergency kit without medication</td>
<td>A convenient kit containing devices and materials for first aid treatment in emergency situations. Usually, it is used in the home, in a car, for emergency services in an ambulance or in crowded venues. This kit does not contain drugs. This kit is for single-use.</td>
<td>44047000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bone wax</td>
<td>A waxy stick, paste, source or ointment used for arresting bleeding from the bone during surgery. Previously, the product was produced from refined beeswax as the raw material. Nowadays, this can be produced from synthetic wax.</td>
<td>10459000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Incision/drainage kit</td>
<td>A package of devices including surgical scalpels and tubes used for creating an opening in the body and placing a drain. This device is for single-use.</td>
<td>35118000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Uterine manipulation set</td>
<td>A set used for injection and excretion of drug solutions, etc. into the uterus while manipulating the uterus. The device consists of a balloon catheter, syringe, tube, and catheter, etc.</td>
<td>70224002</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Abdominal hypobaric patient chamber</td>
<td>A hood-like device used to reduce abdominal pressure in a pregnant woman in order to alleviate abdominal pain during pregnancy or delivery.</td>
<td>32620000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Obstetrical decompression pump</td>
<td>A dedicated pump used with a hood-like device to control and reduce pressure on a pregnant woman. It is used for alleviating abdominal pain during pregnancy or labor.</td>
<td>35283000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Laparoscopy gas pneumoperitoneum device</td>
<td>A dedicated device used to inject pressure-controlled gas into the peritoneal cavity for dilation. The device assists in securing the area under examination or surgery. The device may be capable of maintaining gas pressure in equilibrium by correcting for leakage.</td>
<td>70447000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ophthalmic conformer</td>
<td>An ophthalmic device usually made of molded plastic to be inserted temporarily between the eyeball and palpebra in order to secure space in the orbit and to prevent closure or adhesion during healing after eye enucleation.</td>
<td>16065000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Emergency kit for anaphylaxis</td>
<td>A dedicated kit of the items necessary for emergency care (e.g., drugs, endotracheal tubes) when a patient is in anaphylactic shock. In anaphylactic shock, allergic reactions (shortness of breath, rash, wheezing, and hypotension) are usually observed. The items</td>
<td>16160000</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dialysis start/stop set</td>
<td>A pre-packaged set of single-use instruments and materials (gauze, compress cotton, tweezers, etc.) required at the beginning and end of a dialysis session.</td>
<td>32142000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Surgical tamp</td>
<td>A hand-held surgical device consisting of a handle at the proximal end, an axis, and usually a rectangle, obtuse tip at the distal end. This device is intended to wrap tissues or other substances during surgical procedures.</td>
<td>32873000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use class II surgical procedure kit</td>
<td>A pre-packaged kit that contains all items necessary for ordinary treatment (Class I or Class II), such as various devices, covering protective materials and drugs. This kit is for single-use.</td>
<td>33961002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Single-use circumcision kit A pre-packaged kit, set or tray that contains all items necessary for circumcision, such as various devices, covering protective materials and drugs. It usually includes antiseptics, a circumcision clamp(s), scissors and a scalpel(s). This kit is for single-use.</td>
<td>34945000</td>
<td>II</td>
<td>6</td>
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</tr>
<tr>
<td>Emergency kit for cardiopulmonary resuscitation A kit containing a set of items necessary for performing cardiopulmonary resuscitation (CPR). This kit contains first-aid medicines, endotracheal tubes, face masks, and manual resuscitation bags. This kit is for single-use.</td>
<td>35693000</td>
<td>II</td>
<td>6</td>
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</tr>
<tr>
<td>General-purpose emergency kit for resuscitation A kit packaged in a portable case containing emergency items (e.g., drugs, endotracheal tubes, face masks, manual resuscitation bags) which are stored so as to be ready for use in case of emergency. This kit is strategically located in a hospital. It may also be located in a vehicle that belongs to an emergency department.</td>
<td>36690000</td>
<td>II</td>
<td>6</td>
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<tr>
<td>Ophthalmic insufflator An apparatus used to inject a small volume of air into the eye for retinal reattachment or removal of subretinal fluid in ophthalmic surgery.</td>
<td>37069000</td>
<td>II</td>
<td>6</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable surgical procedure kit A packaged kit, set or tray that contains all items necessary for general surgical treatment, such as various devices, wound covering, protective materials and drugs. This is reusable after being cleansed properly.</td>
<td>37547000</td>
<td>II</td>
<td>6</td>
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<tr>
<td>Puncture needle setting device for ultrasonic probe A fixation device used to mount a puncture needle onto an ultrasonic probe, etc.</td>
<td>70448000</td>
<td>II</td>
<td>5-⑥</td>
<td></td>
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<tr>
<td>Skin grafting peeler A surgical device used to collect skin for skin grafting. It can be used either manually or automatically.</td>
<td>70449000</td>
<td>II</td>
<td>6</td>
<td></td>
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<tr>
<td>Skin grafting dilator A device used to expand a skin graft in order to cover an area larger than the graft. The device enables enlargement at various ratios by making a mesh-like incision on the graft.</td>
<td>70443002</td>
<td>II</td>
<td>6</td>
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<tr>
<td>Anaesthetic filter A device used to remove microorganisms and other foreign bodies from anesthetics and analgesics, etc. The device may also be used to remove air.</td>
<td>70450000</td>
<td>II</td>
<td>2-①</td>
<td></td>
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<tr>
<td>Water for oxygen inhalation warming humidifier Bottled sterilized water used to administer aerosolized water to patients.</td>
<td>70452002</td>
<td>II</td>
<td>5-⑥</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General-purpose surgical irrigation/aspiration unit A device used to perfuse or aspirate fluids in/from a body cavity or any other desired area during surgery for gaining cleaning effect continuously. The device can remove tissue/tissue fragments and fluids, etc. from the cavity/area and keep the cavity/area clean and visible. The device may also be used to facilitate access to a desired area during an operation. The device is often used during cataract surgery. The device must be compatible with the specific surgical procedure.</td>
<td>41643000</td>
<td>II</td>
<td>11</td>
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<tr>
<td>Ophthalmic irrigation/aspiration unit A device used for perfusion with or aspiration of fluids from the eye and orbital cavity in ophthalmic surgery. For example, this device can help the operator by removing fragments, tissues, and fluids from the intervention site, keeping the site clean, and facilitating observation. The device is often used during cataract surgery. The device must be compatible with the specific surgical procedure.</td>
<td>36586000</td>
<td>II</td>
<td>6</td>
<td></td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Applicable</td>
<td>Special Notes</td>
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<tr>
<td>Powered suction unit</td>
<td>An apparatus that can generate negative pressure. It is made up of a vacuum pump, electric motor, gauge, microbiological/moisture filter, overflow trap, and collection bottle or canister. The device is used to aspirate fluids or particulate materials. The device operates on electricity and is usually used when heavy work is required such as surgery.</td>
<td>36777000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Liposuction unit</td>
<td>An apparatus equipped with a powerful pump that can achieve the desired negative pressure and is used with a special cannula for aspirating subcutaneous fat during liposuction. Liposuction is often considered cosmetic surgery.</td>
<td>36894000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thrombus suction unit</td>
<td>A device for providing negative pressure used during thrombectomy in the heart and the pericoronary artery. This device is used to send controlled low pressure generated with the device to a thrombus near the tip of the catheter connected to the device by generating negative pressure.</td>
<td>37232000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
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</tr>
<tr>
<td>Thrombectomy device</td>
<td>A thrombectomy device used to remove a thrombus from the central circulatory system. The device enables aspiration of a thrombus near the tip of the catheter connected to the device by generating negative pressure.</td>
<td>70454000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nasal irrigation/aspiration unit</td>
<td>A device for perfusion and aspiration of the nasal cavity with solutions to enhance the cleaning effect. It is used for removing tissue cores, tissues, fluid, etc. from the treated area, keeping the treated area clean and supporting clearer observation. It may also be used to facilitate easy access to the target area during the procedure.</td>
<td>33579000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
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</tr>
<tr>
<td>Dental bone dust collector</td>
<td>A device used to collect bone debris generated by drilling, etc. during oral surgery.</td>
<td>70455000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Thoracic suction unit</td>
<td>A device that provides negative pressure for removing a large quantity of accumulated body fluid from the thorax (pleural cavity) which is located between the lungs and the chest wall. A large quantity of body fluid is often produced in association with serious internal trauma, damage, surgery, etc.</td>
<td>36787010</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Powered thoracic suction unit</td>
<td>An electric apparatus that provides negative pressure for removal of a large amount of body fluids or air in the chest cavity between the lung and thoracic wall (pleural cavity). A large amount of body fluid is often produced by serious internal trauma, damage, or surgery, etc.</td>
<td>36787020</td>
<td>II</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Low pressure suction unit</td>
<td>An apparatus that generates weak negative pressure used in interventions such as aspiration of fluids or particulate materials. Careful pressure control is necessary to avoid accidental injury when it is used to remove an object blocking the airway in a neonate. The device may run on pressurized gas or other mechanisms.</td>
<td>34860010</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Powered low pressure suction unit</td>
<td>An electric apparatus that generates weak negative pressure (low negative pressure) used to aspirate fluids, gases, and particulate materials, etc. The device may be used to continuously remove from the body (for drainage) fluids, gases, or particulate materials within the thoracic cavity, abdominal cavity, etc. Careful pressure control may be required to avoid accidental injury in cases such as removal of an object blocking the airway of a neonate.</td>
<td>34860020</td>
<td>II</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Manually-operated transportable suction unit</td>
<td>An apparatus that is powered by hand, foot, or both and generates weak negative pressure used in interventions such as aspiration of fluids or particulate materials. The device may be designed for portable or emergency use. The device may also be designed to be integrated into electrical equipment.</td>
<td>36616010</td>
<td>II</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Pressurized gas-powered transportable suction unit</td>
<td>An apparatus that generates negative pressure by the power of pressurized gas (e.g., air, oxygen) and is used in interventions such as aspiration of fluids or particulate materials. The device is designed for portable or emergency use.</td>
<td>36616020</td>
<td>II</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Powered transportable suction unit</td>
<td>An electric apparatus that generates negative pressure and is used in interventions such as aspiration of fluids or particulate materials. The device may be designed for portable or emergency use. The device may be battery-powered.</td>
<td>36616030</td>
<td>II</td>
<td>11</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Powered suction pump</strong></td>
<td>An electrical diaphragm suction pump used in acupuncture/moxibustion. It is connected to a glass or plastic cup that is pressed against the body surface for suction of waste.</td>
<td>36616040</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Powered ovum collection suction unit</strong></td>
<td>An electric apparatus that generates a low flow rate, high suction pressure and is used with a tube, needle, or catheter for aspiration and collection of ovum or oocyte. The device may have an integrated suction pressure regulator.</td>
<td>70456000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Fetal vacuum extractor</strong></td>
<td>A device used to extract the head of a fetus with a vacuum cup.</td>
<td>32596010</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Manually-operated fetal vacuum extractor</strong></td>
<td>A manually operated device used to extract the head of a fetus with a vacuum cup.</td>
<td>32596020</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Abortion suction unit</strong></td>
<td>A device specifically designed for suctioning substances related to conception or menstruation through the cervical duct with the cannula connected to the suction source by using negative pressure. It is designed to remove a fetus and the placenta easily in early abortion (usually, less than 12 weeks' gestation).</td>
<td>32671000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Aspiration tissue biopsy needle unit</strong></td>
<td>A device to which a biopsy needle and other necessary tools are connected for use in resecting tissues by mechanical suction, accompanied by relevant accessories.</td>
<td>70457000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Uterine suction catheter</strong></td>
<td>A semi-rigid or rigid, plastic or metal tubular surgical device inserted into the uterus via cervix using a hard, pointed catheter. The device serves as an aspirator by pulling the piston inside the catheter. The device is intended for single-use.</td>
<td>32655000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
<tr>
<td><strong>Electrosurgical suction tip</strong></td>
<td>A dedicated tip attachment to perform suction in the operative site, specifically designed for electrosurgery. It can be electrically insulated and is usually made of material resistant to the heat generated at the tip. Usually, this device is for single-use.</td>
<td>35509000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>−</td>
</tr>
<tr>
<td><strong>Reusable fibreoptic illuminated suction tip</strong></td>
<td>A device connected to a suction device during surgery or treatment. This device controls or guides the suction, and usually has a built-in optical fiber illuminator for clearer observation of the surgical site. It may have an additional perfusion function such as a</td>
<td>35528000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Surgical suction unit regulator</strong></td>
<td>A device used for adjusting the level of negative pressure by controlling the suction device. Usually, at least two values are set and the operator (a surgeon) selects the level using a foot switch. It is usually used in neurosurgery in order to avoid accidental, excessive</td>
<td>37003000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Thoracic suction unit regulator</strong></td>
<td>A device that controls the suction flow rate by the suction device which is used with a chest drainage system. It is usually made of metal and equipped with a regulatory function and a pressure gauge.</td>
<td>37782000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>EEL Code</td>
<td>Stage</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Tracheal suction unit regulator</td>
<td>A device that controls the level of negative pressure to be applied for removing tracheal secretions. It usually allows continuous suction at various levels of pressure. It is made of metal or plastic. A pressure gauge is built-in to monitor suction pressure.</td>
<td>37783000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use fibreoptic illuminated suction tip</td>
<td>A device attached to an aspirator during a surgical procedure or treatment, used to adjust and control suction. The device usually has an integrated fiber optic light bulb to provide an enhanced view of the surgical site. The device may also have integrated light source for visualization.</td>
<td>38518000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic cement extractor system</td>
<td>A set of devices usually used in combination for removing orthopedic cement from the site to which the cement has been applied during replacement of a cement-fixated artificial joint. It may contain a suction tube, a vacuum trap, and a vacuum source unit for sucking out the cement.</td>
<td>34036000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Airway mucus clearing device</td>
<td>A device for removal of excess secretions (mucus and sputum) from the lungs or airway of a patient who is unable to expel them on his/her own. The device facilitates spitting up of secretions by changing the airway pressure. The device is normally used in just one patient.</td>
<td>43947000</td>
<td>II</td>
<td>5-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Liposuction catheter</td>
<td>A rigid tube inserted into the subcutaneous layer transdermally for removal of fatty deposits. Aspiration is performed with an appropriate unit. This device is for single-use.</td>
<td>36107000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use suction kit</td>
<td>A packaged kit, tray or set that contains various devices, bandages and drugs necessary for the suction procedure. It usually has a few compartments to hold various tools necessary for needle biopsy, suction, and drainage. The tray usually has foamed adhesives applied to the floor of the tray and notches into which sharp devices and needles can be placed.</td>
<td>36142000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transportable suction unit</td>
<td>A device that generates negative pressure used for treatment procedures including suction of fluid or particulate matter. It is operated by pressurized gas such as air or oxygen, by battery, or by hand and foot. It is designed to be used during transportation or in an emergency. “Manually-operated transportable suction unit,” “powered transportable suction unit,” and “pressurized-manpowered transportable suction unit” are excluded.</td>
<td>36616009</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urethral catheter suction unit</td>
<td>A device to suction the dedicated catheter along the urethra at a constant low flow rate using a motor or gear chain. Some types may have a pressure transducer around the catheter tip. Others may record data through a catheter side hole using an external device.</td>
<td>36808000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable suction kit</td>
<td>A packaged kit, tray, or set that contains various devices, bandages and drugs necessary for suction procedures. It usually has a few compartments to store various tools necessary for needle biopsy, suction, and drainage. It usually has foamed adhesives applied to the floor of the tray and notches into which sharp devices and needles can be placed. This device is reusable after being cleansed properly. Some of the accessories need to be changed.</td>
<td>37447000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Enteral suction tube</td>
<td>A hollow device made of plastic or metal with a single or multiple holes. This is used for aspiration of the gastrointestinal tract.</td>
<td>38561000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heart-lung bypass negative-pressure controller</td>
<td>A device used for adjusting the level of negative pressure when vacuum assisted techniques are employed.</td>
<td>70458000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use bladder irrigation kit</td>
<td>A package containing syringes and other devices used for cleansing the urinary bladder. This is for short-term use.</td>
<td>10406002</td>
<td>II</td>
<td>2,5-②</td>
<td>applicable</td>
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<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Functional Category</td>
<td>Applicability</td>
<td>Notes</td>
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</tr>
<tr>
<td>Active device connected dental syringe</td>
<td>An invasive dental device connected to active equipment for cleaning the oral cavity, pulp cavity, and root canal, for removal of foreign bodies and cutting debris.</td>
<td>35970012</td>
<td>II</td>
<td>2, ①, 6, 12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use dental syringe</td>
<td>A single-use, invasive, non-active dental device for cleaning the oral cavity, pulp cavity, and root canal, for removal of foreign bodies and cutting debris. Active devices or those requiring connection to active equipment are excluded.</td>
<td>35970022</td>
<td>II</td>
<td>2, 6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental irrigation probe</td>
<td>A device attached to a handpiece for cleaning (including removal of plaque) of tooth surface and periodontal pockets with mechanical vibration, etc.</td>
<td>70460000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Periodontal pocket irrigation probe</td>
<td>A device attached to a handpiece for cleaning of periodontal pockets, removal of plaque, or measurement of periodontal pocket depth with mechanical vibration, etc.</td>
<td>70461000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Uterine irrigation unit</td>
<td>A device usually specifically designed for the uterus to facilitate collection of a fertilized egg from the uterus.</td>
<td>17520000</td>
<td>II</td>
<td>2, ⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Surgical mist irrigation tip</td>
<td>A device that produces a mist of air or of a mixture of carbon dioxide and air, for washing off blood from a specific surgical area. The device is a chip with a special hole that enables mounting on a suitable tube for delivery of cleaning solution.</td>
<td>18033000</td>
<td>II</td>
<td>2, ⑤, 12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Gastric/colonic lavage unit</td>
<td>A device specifically designed for cleansing the stomach or the colon to remove stimulants or toxic substances, or to clean the cavities before surgery. This is usually operated by a pulsatile flow of sterile water including saline solution.</td>
<td>35994000</td>
<td>II</td>
<td>2, ⑤, 12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic lavage unit</td>
<td>A device used to clean the surgical area for removal of bone tissue and cement during orthopedic surgery. The device usually runs on pulsatile flow of a sterile liquid (e.g., saline solution). The device is usually used in surgery such as artificial joint replacement, bone resection, and surgical fracture fixation.</td>
<td>37026000</td>
<td>II</td>
<td>2, ⑤, 12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use douche kit</td>
<td>A package of a liquid container, connector, flexible catheter, etc. for use in bowel irrigation.</td>
<td>11297002</td>
<td>II</td>
<td>2, ⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ear/nose/throat treatment unit</td>
<td>A unit that supports the patient's body during an otorhinolaryngology (ENT) examination or treatment. The device provides special functions for examination or treatment. Usually it has a table or chair as a part of the system or equipment (aspirator, aerator, drawer for...)</td>
<td>11585000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Air fluidized bed</strong></td>
<td>A bed designed for use in patients who receive treatment for severe and extensive burns. It is also used for the treatment of decubitus ulcers or in patients who have low body fat and need frequent pressure relief. In the bed, a large number of microspheres (ceramic) are used to provide pressure relief. The device may also move pressure points to prevent pressure ulcers.</td>
<td>35921000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Air pressure alleviation pad</strong></td>
<td>A device used mainly for pressure ulcer prevention. It consists of a pump to send air and a mattress to be inflated with air. Some types may prevent pressure from concentrating in one point of the body lying on the mattress filled with air. Other types may move pressure relief areas.</td>
<td>35226000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable decontamination and sterilization washer</strong></td>
<td>A washer used for washing and sterilization of reusable medical apparatuses or devices that are contaminated by organic matter such as blood and necrotic cell fragments. The device usually runs a cleaning cycle that uses either warm or cold water together with a detergent.</td>
<td>14413000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Agar sterilizer</strong></td>
<td>A sterilizer dedicated for agar sterilization and tapping. Agar is a gelatin-like substance obtained from algae and used as a stabilizer or growth medium for microbial culture. The filling and drainage components require sterilization. Steam is usually used for the sterilization medium.</td>
<td>35929000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Moist heat sterilizer for wrapped goods</strong></td>
<td>An apparatus for sterilization of packaged medical devices (e.g., surgical instruments) using steam as an inactivator (sterilizing agent) of microorganisms.</td>
<td>38671010</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Moist heat sterilizer for unwrapped goods</strong></td>
<td>An apparatus for sterilization of non-packaged medical devices (for example, surgical instruments) using steam as an inactivator (sterilizing agent) of microorganisms.</td>
<td>40547010</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Moist heat sterilizer for fluids</strong></td>
<td>An apparatus for sterilization of liquids in hermetic containers using wet heat (usually steam) as sterilizing agent for inactivation of microorganisms.</td>
<td>41450010</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Small agar sterilizer</strong></td>
<td>A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a cycle for sterilization of agar (culture medium) as the main function. The device may also offer a sterilization cycle(s) for packaged/non-packaged non-sterile materials.</td>
<td>70471000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Small wrapped goods moist heat sterilizer</strong></td>
<td>A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a sterilization cycle for packaged surgical instruments, etc. as the main function. The device may offer a sterilization cycle(s) for other materials such as non-packaged surgical instruments, agar (culture medium), and liquids such as drug solutions.</td>
<td>38671020</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Small moist heat sterilizer for unwrapped goods</strong></td>
<td>A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a sterilization cycle for non-packaged surgical instruments, etc. as the main function. The device may offer a sterilization cycle(s) for other materials such as non-packaged surgical instruments, agar (culture medium), and liquids such as drug solutions.</td>
<td>40547020</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Small moist heat sterilizer for fluids</strong></td>
<td>A medical sterilizer using wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a cycle for sterilization of liquids such as drug solutions as the main function. The device may also offer a sterilization cycle(s) for packaged/non-packaged surgical instruments and agar (culture medium). The pressure vessel, the main component of the apparatus, must conform to requirements for a small pressure vessel, simple pressure vessel, or unspecified pressure vessel having a capacity of not less than 0.5 L.</td>
<td>41450020</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dry heat sterilizer</strong></td>
<td>An apparatus for sterilization of medical devices such as surgical instruments using heat in the absence of humidity for inactivation of microorganisms.</td>
<td>35364000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ethylene oxide gas sterilizer</strong></td>
<td>An apparatus for sterilization of medical devices (e.g., surgical instruments) using ethylene oxide gas as sterilizing agent for inactivation of microorganisms.</td>
<td>13740000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Formaldehyde gas disinfecter</strong></td>
<td>An apparatus that disinfects/sterilizes medical devices and facilities, etc. using formaldehyde gas as disinfecting agent for inactivation of microorganisms.</td>
<td>70472000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Chlorine dioxide gas disinfecter</strong></td>
<td>An apparatus that disinfects or sterilizes medical devices or medical facilities, etc. using chlorine dioxide gas as disinfecting agent for inactivation of microorganisms.</td>
<td>70473000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Type</td>
<td>Description</td>
<td>Code</td>
<td>Use</td>
<td>Availability</td>
<td>Comments</td>
<td></td>
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<td>--------------------------------------------------</td>
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</tr>
<tr>
<td>Disinfector for reusable contact lens</td>
<td>A device usually disinfects reusable contact lenses with heat.</td>
<td>10995000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Boiled water sterilizer</td>
<td>An apparatus used for disinfection of medical devices such as surgical instruments using boiled water for a specified period as the medium for inactivation of microorganisms.</td>
<td>31793000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Flexible endoscope disinfectors</td>
<td>A disinfectors designed for decontamination and disinfection of a flexible endoscope. The device houses a processor that allows circulation of disinfectant inside the endoscope lumen. The device may also be capable of drying the cleaned endoscope.</td>
<td>35628000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable rigid endoscope decontamination disinfectors</td>
<td>A disinfectors designed for decontamination and disinfection of a reusable, rigid endoscope. The device has a function to circulate disinfectant inside the endoscope lumen. The device may also be capable of drying the cleaned endoscope.</td>
<td>35981000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Cold liquid sterilizer</td>
<td>An apparatus used for disinfection of medical devices such as surgical instruments and flexible/rigid endoscopes using solutions, etc. that inactivate microorganisms. The goods to be disinfected are placed in a tray or bucket and immersed in the cleaning solution, etc. for a specified period.</td>
<td>36253000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Formaldehyde gas sterilizer</td>
<td>An apparatus used for sterilization of medical devices such as surgical instruments using formaldehyde gas as sterilizing agent for inactivation of microorganisms.</td>
<td>40583000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultraviolet water purification unit</td>
<td>An apparatus for water purification using a UV disinfection lamp that generates short-wavelength radiation and kills bacteria, viruses, and other microorganisms in water.</td>
<td>35435000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Water sterilizer</td>
<td>An apparatus that produces sterile water used by surgeons and surgical assistants for handwashing.</td>
<td>70475000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Plasma gas sterilizer</td>
<td>An apparatus used for sterilization of medical devices such as surgical instruments using plasma gas as sterilizing agent for inactivation of microorganisms. Plasma refers to a grom of reaction products generated by excitation of ions, electrons, and free radicals in</td>
<td>36305000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Microwave sterilizer for unwrapped goods</td>
<td>A device used for sterilizing individual surgical devices, etc. unpackaged as a set. It utilizes microwaves as the heating source to inactivate microorganisms.</td>
<td>37494000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Microwave sterilizer for wrapped goods</td>
<td>A device used for sterilizing surgical devices, etc. packaged as a set. It utilizes microwaves as the heating source to inactivate microorganisms.</td>
<td>37495000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Microwave sterilizer for fluid</td>
<td>A device used for sterilizing solutions, etc. filled into hermetic containers, etc. It utilizes microwaves as the heating source to inactivate microorganisms.</td>
<td>37509000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
<td>Additional Information</td>
</tr>
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</tr>
<tr>
<td>Hydrogen peroxide gas sterilizer</td>
<td>An apparatus used for sterilization of medical devices such as surgical instruments using hydrogen peroxide gas as sterilizing agent for inactivation of microorganisms.</td>
<td>40567000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Chlorine dioxide gas sterilizer</td>
<td>A device that uses chlorine dioxide gas as a sterilant to inactivate microorganisms and sterilizes medical devices including surgical devices.</td>
<td>40571000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Heat bone disinfector</td>
<td>An apparatus that can disinfect bone grafts for human femoral head replacement by heating at a specified temperature (80°C to 90°C) for a specified period (10 minutes) in a hermetic aseptic container using sterile water (e.g., saline solution) as the (thermal)</td>
<td>70476000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Strongly acidic water electrolyzer</td>
<td>An apparatus that can continuously produce an acidic aqueous solution (strongly acidic electrolyzed water) containing hypochlorous acid derived from the anode by electrolysis of tap water after addition of a small amount of sodium chloride in a diaphragm electrolysis</td>
<td>70477000</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood refrigerator</td>
<td>A cooling apparatus specifically designed to preserve blood and blood components such as whole blood, blood cells, and plasma at a constant temperature. The device has an integrated alarm that tells an unexpected temperature elevation. The device may also be used at blood donation centers. It keeps blood in motion during transfer from the donor to the blood bag placed inside the cradle of the device.</td>
<td>35486000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood donation blood rocker</td>
<td>A device that can keep blood homogeneous by continuous shaking. The device is usually used at blood donation centers.</td>
<td>36405000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Heart preservation/transport system</td>
<td>A special container that holds and preserves the heart donated during transportation to the hospital where the recipient awaits heart transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.</td>
<td>37276000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Kidney preservation/transport system</td>
<td>A special container that holds and preserves the kidney donated during transportation to the hospital where the recipient awaits kidney transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.</td>
<td>33479000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Liver preservation/transport system</td>
<td>A special container that holds and preserves the liver donated during transportation to the hospital where the recipient awaits liver transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.</td>
<td>42919000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Intestine bag</td>
<td>A flexible container used temporarily during surgery to protect the intestine from water loss.</td>
<td>33522000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Portable continuous peritoneal perfusate thermal conditioner</td>
<td>A device that heats the peritoneal perfusate before injection into the peritoneal cavity. The perfusate is usually heated through direct contact of the dialysis fluid bag with the radiant heat source.</td>
<td>70478002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Tissue culture vessel</td>
<td>A culture vessel or a polymeric or metallic material to be a scaffold for cells that is used for tissue culture.</td>
<td>70480000</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Valve prosthesis rotator</td>
<td>A surgical device used for heart valve replacement. It is used for changing direction of the flow in an artificial valve.</td>
<td>70483009</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Level</td>
<td>Applicable</td>
<td>Notes</td>
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<td>---------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Percutaneous pacemaker electrode extractor</td>
<td>A composite device used for removal of a pacemaker electrode by making a small incision in the skin. This device incorporates a small clamp holding an electrode and a device designed to remove tissue adhering to the electrode. The device may have a loop that slides along the electrode to remove the adhering tissue or a laser to resect the adhering tissue.</td>
<td>34235000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>External cardiac pacemaker transesophageal electrode</td>
<td>An electrode placed in the esophagus to establish an electric connection for the purpose of delivery of electrical impulses sent from a transesophageal external cardiac pacemaker. This is a non-invasive device for temporary use.</td>
<td>41474000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Steerable stylet</td>
<td>A movable device temporarily used for assistance in positioning the leads of pulse generator or in moving their positions.</td>
<td>70486000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urological stent repositioning catheter</td>
<td>A catheter used to make a small adjustment in the position of a ureteral stent after its placement.</td>
<td>70492000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Orthopaedic rotator</td>
<td>A transplant device or accessories of the brace used to support, protect or assist the use of the cast, brace or transplant device for the purpose of medical care.</td>
<td>35487000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Positioning sensor</td>
<td>A device that detects movement or reacts to movement and sends signals that are proportional to the level of movement. The base unit reacts to the signal sent from the sensor or the signal indicating the location of the object to which the sensor is attached, and displays or controls the target object for monitoring. It can be attached to the leg of a patient as an aid to determining precise positioning of a prosthetic hip during hip replacement using a computer.</td>
<td>43267000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheostomy speech valve</td>
<td>A device connected to an endotracheal tube to enable the patient to speak without the use of a hand/finger for closing the opening. The device enables patients with tracheostomies to speak more easily and clearly.</td>
<td>36071000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Syringe for implantation</td>
<td>A hollow tube with a threaded plunger and pressure gauge, used to implant other instruments such as embolization implant. After surgically positioned at the target site of an injury or obstruction of the duct that transports sperm from the epididymis to the urethra. This is for short-term use.</td>
<td>43989000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Short-term use vas deferens prosthesis</td>
<td>A device used to repair the site of an injury or obstruction of the duct that transports sperm from the epididymis to the urethra. This is for short-term use.</td>
<td>31995002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dialyser connector</td>
<td>A connector between a dialysis fluid circuit and dialyzer, etc.</td>
<td>70516000</td>
<td>II</td>
<td>2-3</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Extracorporeal circulation hematocrit monitor measuring cell</td>
<td>A cell used to determine the hematocrit level (percentage of red blood cells) invasively during extracorporeal circulation in hemodialysis or open heart surgery. It is usually attached to an extracorporeal circulation device.</td>
<td>70519000</td>
<td>II</td>
<td>2-3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heat exchanger for heart-lung bypass</td>
<td>A heat exchange system used during extracorporeal circulation for heating or cooling the blood or the perfusate for cardiopulmonary bypass or treatment.</td>
<td>11973112</td>
<td>II</td>
<td>3-4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heart-lung bypass system blood reservoir</td>
<td>A device used as part of the heart-lung bypass pump or used together with other devices during short-term extracorporeal circulation to maintain blood reserve for extracorporeal circulation. The device may have a filter. The device is intended for single-use.</td>
<td>31710102</td>
<td>II</td>
<td>2-3</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heart-lung bypass defoamer</td>
<td>A device used to remove bubbles from the blood during cardiopulmonary bypass. This is used with an oxygenator that adds the required amount of oxygen to the blood before the blood returns to the patient.</td>
<td>31711112</td>
<td>II</td>
<td>3-4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heart-lung bypass filter</td>
<td>A filter used to prevent particles and blood clots from entering the bloodstream and obstructing extracorporeal circulation. This filter may be used for trapping air bubbles.</td>
<td>33309102</td>
<td>II</td>
<td>3-4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicability</td>
<td>Notes</td>
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</tr>
<tr>
<td><strong>Cardioplegic solution filter</strong></td>
<td>A filter used to remove foreign bodies from cardioplegic solution and to prevent their obstructing extracorporeal circulation. The device may also be capable of removing microaggregates and bubbles from blood cardioplegic solution.</td>
<td>70525000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Single-use defoamer for heart-lung bypass</strong></td>
<td>A device used to remove bubbles from blood during cardiopulmonary bypass. The device is used with an oxygenator, which adds the required amount of oxygen to blood before the blood returning to the patient. The device is intended for single-use.</td>
<td>31711122</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Single-use heart exchanger for heart-lung bypass</strong></td>
<td>An apparatus incorporating a heat exchange system used during extracorporeal circulation. The device warms or cools blood or the perfusate for cardiopulmonary bypass or treatment. The device is intended for single-use.</td>
<td>11973122</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Hemodialysis blood tubing</strong></td>
<td>A single-use sterilized blood tubing intended for hemodialysis (including hemofiltration and hemodiafiltration). Usually, it consists of a tube assembly (connectors, clamps, etc.) necessary for introducing blood or other solutions through a vascular access device into an extracorporeal circuit.</td>
<td>34999102</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ventricular vent suction control valve</strong></td>
<td>An adjustable or non-adjustable valve designed to be attached to the left ventricular (LV) line to maintain weak suction so that the line remains in place. The device is used to decrease left ventricular pressure during cardiopulmonary bypass.</td>
<td>17581000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Connector for tube for blood tubing</strong></td>
<td>A connector that is used to join two tubes. The device is used in a blood tubing, etc.</td>
<td>70545102</td>
<td>II</td>
<td>2-②</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Plasma separation blood tubing</strong></td>
<td>A blood tubing used with a membrane plasma separator, plasma fractionation membrane, or selective adsorption column for plasma fractionation, etc. for blood purification through extracorporeal circulation. The device is intended for single-use.</td>
<td>70546000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Transducer protection filter</strong></td>
<td>A device for removal of foreign bodies from the gas line during pressure monitoring.</td>
<td>70547000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Blood tubing for slow continuous hemofiltration</strong></td>
<td>A blood tubing for slow continuous hemofilter which purifies the blood through extracorporeal circulation. The device is intended for single-use.</td>
<td>70549000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Ascites filtration and reinfusion system blood tubing</strong></td>
<td>A blood tubing used with concentrated ascites reinfusion system to drain ascites or pleural effusion and return fluid to the bloodstream after filtration and concentration. The device is intended for single-use.</td>
<td>70550000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Blood tubing for blood cells removal</strong></td>
<td>A blood tubing used with a cytapheresis column for removal of blood cells through extracorporeal circulation. The device is intended for single-use.</td>
<td>70551000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Hemofiltration blood tubing</strong></td>
<td>A blood tubing used with a hemofilter for blood purification through extracorporeal circulation. The device is intended for single-use.</td>
<td>70552000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Blood tubing for adsorption hemoperfusion</strong></td>
<td>A blood tubing used with an adsorption blood purification device. The device is intended for single-use.</td>
<td>70553000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
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<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
<th>Code</th>
<th>Class</th>
<th>Category</th>
<th>Remarks</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood tubing for endotoxin removal adsorption hemoperfusion</td>
<td>A blood tubing used with an adsorption blood purification device for endotoxin removal through extracorporeal circulation. The device is intended for single-use.</td>
<td>70554000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood tubing for centrifugal apheresis unit</td>
<td>A blood tubing used with a centrifugal apheresis system for separation and collection of blood components. The device is intended for single-use.</td>
<td>70555000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Circuit for centrifugal hemoperfusion unit</td>
<td>A blood tubing attached to a centrifugal blood purification device for purification concentration or other process of blood components, etc. The device is intended for single-use.</td>
<td>70556000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood tubing for centrifugal blood component sampling unit</td>
<td>A blood tubing through which blood components are separated and collected with a centrifugal blood component collection device. This device is for single-use.</td>
<td>70557000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood tubing for multipurpose blood treatment</td>
<td>A blood tubing used with a membrane plasma separator, slow continuous hemofilter, or cytapheresis column etc. for multi-purpose processing of blood such as blood cell removal or blood purification etc. through extracorporeal circulation. The device is intended for single-use.</td>
<td>70558000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Priming solution filter for heart-lung bypass system</td>
<td>A single-use device for filtration of non-heme priming solution for a heart-lung circuit system.</td>
<td>36080000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Blood tubing for monitoring set</td>
<td>A tube connecting a blood tubing and sphygmomanometer. The device is sometimes integrated into a blood tubing. The end connected to a blood tubing may have a Luer taper, or it may be a needle.</td>
<td>70559000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Breathing circuit filter</td>
<td>A sieve placed in a gas supply line. The device captures bacterial pathogens by the pore size or electrostatic charge. The device is usually used in ventilation systems or a gas</td>
<td>35070000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Gas delivery line filter</td>
<td>A fine-pore (&lt;100 μm) membrane that is capable of capturing fine particles present in gases, and is connected to a gas line. The device can minimize the risk of transmission of</td>
<td>35534000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Suction unit filter</td>
<td>A sieve installed in or connected to an aspirator. The pore size in the membrane is small enough to capture bacterial pathogens. Therefore, the device prevents environmental infection and reduces the risk of cross infection to another patient.</td>
<td>37798000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Heated humidifier</td>
<td>A device used to warm and humidify gases in a patient circuit that are delivered from a ventilator, etc.</td>
<td>70562000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
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<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>EHTL</td>
<td>Applicable</td>
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<tr>
<td>IMV supplement ventilator breathing circuit</td>
<td>A device comprising a tube and one-way valve, designed for mandatory ventilation for patients with a ventilator in order to supplement the spontaneous respiratory rate. The device may be used as an attachment to an old respirator without the capability for intermittent mandatory ventilation (IMV).</td>
<td>16803000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
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</tr>
<tr>
<td>Reusable IMV supplement ventilator breathing circuit</td>
<td>A device designed to provide mandatory ventilation for a patient with a ventilator in order to supplement the spontaneous respiratory rate. It is usually made of durable materials and consists of tubes and one-way valves. This device is reusable after being cleansed and sterilized as recommended.</td>
<td>42909000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use breathing circuit connector</td>
<td>A single-use device used to connect a respiratory circuit to an endotracheal tube, face mask, and other components of the respiratory circuit. Because the outer and inner diameters of the tube are standardized respectively to 22 mm and 15 mm by ISO, it may be used to adjust the size of respiratory tubes for pediatric and adult patients. The device is made of plastic or metal. Some design variants enable partial rotation at the joint. The device is intended for single-use.</td>
<td>34838012</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable breathing circuit connector</td>
<td>A device used to connect a respiratory circuit with an endotracheal tube, face mask, and other components of the ventilator circuit. Because the outer and inner diameters of the tube are standardized respectively to 22 mm and 15 mm by ISO, it may be used to adjust the size of respiratory tubes for pediatric and adult patients. The device is made of plastic.</td>
<td>34838022</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tracheal tube adaptor</td>
<td>A connecting device, which is usually a small part, used for connecting the endotracheal tube to the breathing circuit or manual resuscitator in order to make them mutually compatible and establish a connection between them.</td>
<td>35400000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable ventilator breathing circuit</td>
<td>A device for transmission of air or oxygen-rich gas from a ventilator to the patient. The device may be connected to devices for humidification, drug administration, and monitoring of gas concentration/pressure in a respiratory circuit. The device is reusable.</td>
<td>37705000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use ventilator breathing circuit</td>
<td>A single-use device for transmission of air or oxygen-rich gas from a ventilator to the patient. The device may be connected to devices for humidification, drug administration, and monitoring of gas concentration/pressure in the respiratory circuit.</td>
<td>37706000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Breathing circuit set</td>
<td>A ventilator set including a ventilator circuit, water trap, nebulizer, filter, mask, pressure-regulating valve, connector, rebreathing bag, etc. Heated humidifier itself is excluded.</td>
<td>70566000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Anesthetic breathing circuit set</td>
<td>An anesthetic breathing circuit set including a ventilator circuit, water trap, nebulizer, filter, mask, pressure-regulating valve, connector, anesthetic bag, etc. Heated humidifier itself is excluded.</td>
<td>70567000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-anesthetic breathing circuit bag</td>
<td>A bag that houses breathing gas in the breathing circuit.</td>
<td>70568000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Gas delivery tube for breathing circuit</td>
<td>A tube for supplying gases into a breathing circuit, connected to a mask, etc.</td>
<td>70569000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aerosol non-rebreathing mask</td>
<td>A flexible, cone-shaped device placed over the patient's nose and mouth to deliver air, oxygen, or a mixture of air and oxygen, which contains aerosolized particles, to the airway. The device has two one-way valves, one that closes during inspiration so that room air does not get mixed with oxygen inside the reservoir bag, and the other that closes during exhalation so that exhaled gas does not enter the reservoir bag.</td>
<td>35172000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Air/oxygen non-rebreathing mask</td>
<td>A flexible, cone-shaped device placed over the patient's nose and mouth to deliver high-concentration oxygen mixed with air to the airway. The device has two one-way valves, one that closes during inspiration so that room air does not get mixed with oxygen inside the reservoir bag, and the other that closes during exhalation so that exhaled gas does not enter the reservoir bag. The device is intended for single-use.</td>
<td>35173000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Partial rebreathing mask</td>
<td>A device used to deliver a mixture of air and oxygen to the patient's airway. The device is equipped with a reservoir bag that allows the patient to inhale a mixture of exhaled and fresh gases. The device is usually connected to the oxygen source via a tube. The device has a head strap for fixation. The device is made of plastic.</td>
<td>35174000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Venturi mask</td>
<td>A flexible, cone-shaped device placed over the patient's nose and mouth to deliver a mixture of an almost precise ratio of air and oxygen to the patient's airway. The device usually has a replaceable part (Venturi tube) to change the mixture ratio of air and oxygen.</td>
<td>35175000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Resuscitation mask</td>
<td>A flexible, cone-shaped device placed over the patient's nose and mouth to deliver oxygen during cardiopulmonary resuscitation (CPR). The device is designed to substitute mouth-to-mouth resuscitation to prevent cross-infection. The device is also used with manikins during CPR training. The device may come with an airway one-way valve and other.</td>
<td>36066000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Heated humidifier</td>
<td>An apparatus that is connected to the inspiratory line and increases the humidity and temperature of gases that enter the patient's lungs by delivering warmed vapor to the line.</td>
<td>12050000</td>
<td>II</td>
<td>2-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use heat/moisture exchange humidifier</td>
<td>A device that captures the heat and moisture from a patient, and heats and moisturizes the inspired gas by utilizing the heat and moisture of the patient, when connected to the patient's artificial airway through the line. It is a passive canister type device and also called an artificial nose.</td>
<td>35530000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Artificial nose</td>
<td>A passive, canister-shaped apparatus (artificial nose) that captures and uses the heat and moisture in exhaled air to heat and humidify inspiratory air, when connected in line with the patient's artificial airway. This device has one port each for the patient and the ventilator and is connected to a respirator/anesthetic apparatus.</td>
<td>70570000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Artificial nose for tracheostomised patients</td>
<td>A passive, canister-shaped apparatus (artificial nose) that captures and uses the heat and moisture in exhaled air to heat and humidify inspiratory air, when connected in line with the patient's artificial airway. This device has only one port for the patient (no port for any apparatus), and is connected to the tracheostoma of a patient breathing spontaneously.</td>
<td>70571000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Single-use artificial nose filter</td>
<td>A passive, single-use, canister-shaped apparatus that is connected by tube in line with the patient's artificial airway and is designed to remove foreign bodies and captures and use heat and moisture in exhaled air to heat and humidify inspiratory air. The device is also connected to a respirator/anesthetic apparatus.</td>
<td>70572000</td>
<td>II</td>
<td>3-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable heat/moisture exchange humidifier</td>
<td>A device that captures the heat and moisture from a patient, and heats and moisturizes the inspired gas by utilizing the heat and moisture of the patient, when connected to the patient's artificial airway through the line. It is a passive canister type device used with a</td>
<td>41189000</td>
<td>II</td>
<td>5-6①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Single-use anaesthesia breathing circuit</strong></td>
<td>A device used to deliver medical gas to the patient from the fresh gas feeder of an anaesthesia system. The respiratory system may connect the patient, ventilator, circle absorber and a connector of monitor. The device usually has two passages for inspiration.</td>
<td>37704000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Scavenging anaesthesia mask</strong></td>
<td>A cylinder-shaped device placed over the patient’s nose and mouth to deliver anesthetic or analgesic gas to the patient. The device has soft edges fitted to the anatomical form of the patient’s face to eliminate the gap and an outer casing or other structure that delivers.</td>
<td>33523000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable to-and-fro absorption anaesthesia breathing circuit</strong></td>
<td>A respiratory system connected between the reservoir bag and the patient port. This device divides the air flow passing through a carbon dioxide absorber in two directions. This device is reusable.</td>
<td>34433000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use anaesthesia breathing circuit bag</strong></td>
<td>A single-use, reservoir bag made of elastomer and used to preserve respiratory air in the respiratory circuit. The device is set to the inspiratory or expiratory limb of the respiratory circuit, depending on the circuit design. The device may function as a maximum pressure limiter during spontaneous breathing or manually assisted.</td>
<td>34877000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Anaesthesia mask</strong></td>
<td>A flexible, cone-shaped device that is made of conductive or non-conductive rubber or other materials and placed over the patient’s nose or mouth for delivery of anesthetic gas to the upper airway. The device is sometimes used with a resuscitator.</td>
<td>35176000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Halogenated vapour absorber</strong></td>
<td>A canister containing absorbents (e.g., activated charcoal) that remove halogenated steam from the respiratory system or expired gas.</td>
<td>36096000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable carbon dioxide absorber</strong></td>
<td>A refillable container, used with the respiratory circuit of an anesthesia system for removal of carbon dioxide on expiration. The device is reusable after refilling of the carbon dioxide absorbent inside and subsequent steps necessary for hygiene.</td>
<td>37022000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable anaesthesia breathing circuit bag</strong></td>
<td>A reservoir bag made of elastomer and used to retain respiratory gas in the respiratory circuit. The device is set to the inspiratory or expiratory limb of the respiratory circuit, depending on the circuit design. The device may function as a maximum pressure limiter during spontaneous breathing or manually assisted ventilation. This device is reusable.</td>
<td>37709000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Single-use carbon dioxide absorber</strong></td>
<td>A pre-packaged container of carbon dioxide absorbent used with the respiratory circuit of an anesthesia system. The device is used with a respiratory circuit for removal of carbon dioxide on expiration. The device is intended for single-use.</td>
<td>42414000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Reusable anaesthesia breathing circuit</strong></td>
<td>A device used to deliver medical gas from the fresh gas feeder of an anesthesia system to the patient. The respiratory system may connect the patient, ventilator, circle absorber, and a connector of monitor. The device usually provides two passages for inspiration and expiration. There are rebreathing and non-breathing systems. The device may be other.</td>
<td>37021000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Tympmonic membrane anesthesia apparatus</strong></td>
<td>A device for applying weak electric current in the target site during otorhinolaryngology (ENT) surgery to facilitate absorption of anesthetic into the tympanic membrane. The device includes electrodes for the ear and arm as accessories.</td>
<td>70574000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Iontophoretic tympanic membrane anesthesia apparatus</strong></td>
<td>An apparatus that facilitates absorption of anesthetic solution into the tympanic membrane by applying weak electric current to the human body (iontophoresis).</td>
<td>70575000</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Nasal oxygen cannula</strong></td>
<td>A semi-rigid tube and prongs used to deliver oxygen to the patient via nostrils. The device is intended for single-use.</td>
<td>35201000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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</tr>
<tr>
<td>Continuous positive airway pressure nasal cannula</td>
<td>The semi-rigid tube and prongs used for delivery of oxygen during continuous positive airway pressure (CPAP).</td>
<td>35202000</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Nasal oxygen delivery cannula</td>
<td>A flexible tube inserted into the nostrils to deliver supplementary oxygen into the nasopharynx.</td>
<td>35203000</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Air/oxygen mask</td>
<td>A flexible, cone-shaped device placed over the patient’s nose and mouth to deliver air and oxygen gas to the airway. The device is usually non-conductive. The device may have a strap, a connector(s), a valve(s), etc.</td>
<td>35171000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Air/oxygen tracheostomy mask</td>
<td>A device used for delivery of oxygen or a mixture of air and oxygen to a patient with a tracheostomy tube. The device is usually connected to the oxygen source via a tube, a breathing tube, etc.</td>
<td>35178000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Aerosol tracheostomy mask</td>
<td>A device used for delivery of air, oxygen, or a mixture gas of air and oxygen mixed with aerosolized water to a patient with a tracheostomy tube. The device is usually connected to the oxygen source or nebulizer via a breathing tube, etc.</td>
<td>35179000</td>
<td>II</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Oxygen administration kit</td>
<td>A kit that includes devices for oxygen administration. The devices include a mask, nasal prongs, oxygen tubing, and a connector.</td>
<td>12855000</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Oxygen therapy flowmeter</td>
<td>A device used for administration of pure oxygen (O2). The device is used to treat critically ill patients (e.g., those with myocardial infarction, hypoxia, or postoperative deterioration). The device may have a function of humidification and is connected to a medical oxygen cylinder and oxygen delivery system, to the patient through nasal cannulas.</td>
<td>37132000</td>
<td>II</td>
<td>2-1,11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Synchronised respiration oxygen conserving regulator</td>
<td>A device used to regulate the rate of flow of oxygen delivered from an apparatus, such as a medical oxygen cylinder and oxygen delivery system, to the patient through nasal cannulas.</td>
<td>70576000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Oxygen controller</td>
<td>A device used to measure and regulate oxygen concentration during oxygen therapy.</td>
<td>70577000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>CPAP kit</td>
<td>A kit that includes devices used to provide continuous positive airway pressure (CPAP), allowing delivery of oxygen and air to the patient at a controlled rate. The devices include a mask, nasal prongs, a respiratory circuit, and connector.</td>
<td>70579000</td>
<td>II</td>
<td>5</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Set for synchronised respiration oxygen conserving regulator</td>
<td>A device used to regulate the rate of flow of oxygen delivered from an apparatus, such as a medical oxygen cylinder and oxygen delivery system, to the patient through nasal cannulas. This may also include a regulator, oxygen tube, and nasal cannulas.</td>
<td>70580000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use oxygen generating oxygen supply unit</td>
<td>A device used for first aid. The device supplies a constant quantity of oxygen for a short time (for around 12 minutes) by chemically generating oxygen. This consists of a mask, a tube and an oxygen generator, and may have an oxygen generation indicator. This device is for single-use.</td>
<td>70581000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Oxygen concentrator</td>
<td>An apparatus that removes nitrogen from room air by passing air through an adsorption column or a membrane with a large surface area. Apparatuses for medical gas pipeline systems (JIS T7101) are excluded. The components of the apparatus include a compressor, filter, and reservoir. Oxygen concentration is regulated based on flow rate. For those to be regulated, the pressure regulator has to be included.</td>
<td>12873002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Liquid oxygen vaporization unit set</td>
<td>A device that vaporizes liquid oxygen, depressurizes the oxygen and supplies it to a patient. This incorporates a liquid oxygen container, a heating coil, a relief economizer valve, a pressure regulator, etc. The oxygen concentration varies according to the applied flow rate. This device may have an oxygen supply tube, a nose cannula, etc. to supply oxygen.</td>
<td>70582000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Liquid oxygen vapor unit</td>
<td>An apparatus that vaporizes liquid oxygen and delivers oxygen to the patient at a reduced pressure. Apparatuses for medical gas pipeline systems (JIS T7101) are excluded. The components include a liquid oxygen container, heating coil, relief/economizer valve, pressure regulator, etc.</td>
<td>70583000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Open infant incubator</td>
<td>A unit that functions like a standard incubator but has lower side walls and no hood, allowing contact with the infant inside. The unit is intended not for premature babies but for infants with a disease which requires as intensive a care as that in an incubator. The unit has an overhead heating lamp, oxygen flowmeter, gas mixer, aspiration unit, unit for an infusion pump, etc. This differs from a closed incubator in that it cannot control the ambient oxygen levels for the infant inside.</td>
<td>36742000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Stationary infant radiant warmer</td>
<td>An apparatus that has an integrated infrared heating element and is designed to irradiate heat evenly over a neonate or infant who needs a controlled heat environment. The device is normally kept in a ward or treatment room. Although the device may have a treatment table for a patient in respiratory arrest) to supply heat to the patient concerned from above. This is usually used for warming a newborn baby or a neonate that needs</td>
<td>17956000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Infant regional heating unit</td>
<td>A device designed to utilize radiant heat, to be used alone or with other devices (e.g., a treatment table for a patient in respiratory arrest) to supply heat to the patient concerned from above. This is usually used for warming a newborn baby or a neonate that needs</td>
<td>36812000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Peritoneal dialysis ultraviolet irradiation unit</td>
<td>A device that provides ultraviolet irradiation for disinfection of connection area when components of peritoneal dialysis transfer tube set are connected. The device may have a connecting function.</td>
<td>17434000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Regional perfusion heat exchanger</td>
<td>A special device that warms the blood by transmitting heat through the membrane. This is used for perfusion of the limbs or the organs except the heart.</td>
<td>13318000</td>
<td>II</td>
<td>3①</td>
<td>applicable</td>
<td>N/A</td>
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<td>Device/Equipment</td>
<td>Description</td>
<td>Code</td>
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<td>Applicability</td>
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<tr>
<td>Peritoneal perfusate filter</td>
<td>A device that has pores through which contaminated particles in the peritoneal perfusate are captured before it is injected into the peritoneal cavity.</td>
<td>33627000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood recovery unit</td>
<td>A blood salvage machine with the ability to wash cells, for immediate or subsequent re-transfusion of the patient's blood lost during surgery or due to trauma. The blood salvage process commonly involves separation of red blood cells and subsequent washing with saline solution (NaCl), etc. The machine is used for blood collection and cell washing only.</td>
<td>34863002</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use autotransfusion kit</td>
<td>A single-use set consisting of a centrifuge bowl, blood bag, etc. that are specifically designed to be used with a blood salvage machine with the ability to wash cells, for immediate or subsequent re-transfusion of the patient's blood lost during surgery or due to trauma.</td>
<td>70597000</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Gait neuromuscular electrical stimulator</td>
<td>A type of electrical neuromuscular stimulator that stimulates the lower extremity nerves (e.g., peroneal nerve, femoral nerve), and induces muscular contraction in the lower extremities to improve the locomotor function in patients with partial paralysis of the lower limbs.</td>
<td>35725000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Scoliosis neuromuscular electrical stimulator</td>
<td>A type of stimulator that increases strength by stimulating the muscular tissues of the back to stabilize a scoliotic spine (scoliosis) or to delay disease progression. Some types may utilize an embedded receiver with electrodes and an external transmitter. However, the majority of stimulators are external types and utilize surface electrodes attached to the skin.</td>
<td>36006000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Multifunctional muscle electrical stimulator</td>
<td>A device that assists and controls biological functions through electrically stimulating the peripheral muscles paralyzed by neurological disorders. Stimulation methods include a method with surface electrodes, and a method with embedded electrodes.</td>
<td>70598000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Breathing circuit gas sensor</td>
<td>A device that detects gases inside the respiratory circuit. The device is usually mounted on an anesthetic ventilator, etc. The device is designed for monitoring of gas inflow and outflow, to or from a patient. The base unit displays incoming signals and controls monitored parameters in response.</td>
<td>36849000</td>
<td>II</td>
<td>2-①</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Infrared light therapy unit</td>
<td>An apparatus used for the treatment of rigors, pain, and inflammation by providing warmth. The device transmits infrared light at a wavelength of 600 to 1200 nanometers (nm). The device is sometimes used for disease management/treatment in neonates who require phototherapy for jaundice.</td>
<td>35147000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultraviolet light therapy unit</td>
<td>An apparatus with a special lamp that irradiates ultraviolet light. The device is usually used for the treatment of skin disorders (psoriasis). The device has a ceiling light (hanging light unit) with UV light tubes that irradiate UV light evenly for systemic exposure. The device is often used with psoralen for psoralen UVA (PUVA) therapy.</td>
<td>35149000</td>
<td>II</td>
<td>9</td>
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<td>Description</td>
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<td>Code</td>
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<tr>
<td>Carbon arc light therapy unit</td>
<td>A device used for skin treatment (e.g., heliotherapy), equipped with special carbon rods that generate ultraviolet light; this device uses conventional techniques.</td>
<td>34476000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Neonatal jaundice light therapy unit</td>
<td>An apparatus that transmits a blue, green, or white light and is used to treat neonatal jaundice, etc.</td>
<td>35239000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Seasonal affective disorder light therapy unit</td>
<td>A device used for patients with seasonal affective disorder (SAD). This device imitates ordinary daylight to improve the patient's mental state.</td>
<td>34091000</td>
<td>II</td>
<td>9</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Xenon beam light therapy unit</td>
<td>An apparatus that improves neural reflexes, enhances blood flow by warming, activates tissues, and relieves pain/inflammation, etc. by irradiation with a continuous spectrum of UV light, visible light, and infrared light generated by a xenon discharge tube. The device provides preset control options for emission pulse, duration, etc.</td>
<td>70606000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Low frequency therapy equipment</td>
<td>An apparatus that stimulates nerves and muscles percutaneously for relief of pain and muscle atrophy. The device consists of a stimulus generator and electrodes. Electrodes are placed on the skin (not inserted). Electrical stimulation is delivered through the skin (percutaneously) to the area of pain or muscle abnormality. Usually, electrical stimulation can be adjusted using preset control options (pulse frequency, duration, etc.). The device provides preset control options for emission pulse, duration, etc.</td>
<td>35372000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Interference low frequency therapy equipment</td>
<td>An apparatus intended for the treatment of muscular and painful disorders. The device delivers 2 types of medium-frequency (MF) current, designed to provoke interference from multiple pairs of skin electrodes. The currents produce a beat frequency, commonly used in the treatment of muscle disorders, at the difference of the frequencies. A beat frequency suitable for pain relief is produced at higher frequencies. The skin electrodes may come in.</td>
<td>36737000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Low frequency therapy equipment electrode</td>
<td>A conductor used with a low-frequency therapy device. It is placed on the patient's body to transmit electromagnetic energy from a base unit.</td>
<td>34479000</td>
<td>II</td>
<td>5-6</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Strength-duration measurement low frequency therapy equipment</td>
<td>A device for nerve/muscle stimulation that is used percutaneously for the relief of pain and muscle atrophy and can display an intensity-duration curve. An intensity-duration curve is obtained by plotting the minimum electrical current that induces muscle.</td>
<td>70607000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Microwave therapy system</td>
<td>A therapeutic apparatus that transmits a beam of high-frequency microwaves for heating body tissue at a depth of 1 to 2 cm under the skin, to facilitate cure or relieve pain. Unlike surgical diathermy, the tissue is heated but not damaged.</td>
<td>11245000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ultra-short wave therapy unit</td>
<td>A therapeutic apparatus that delivers radiofrequency (13 to 27.12 MHz) electromagnetic radiation to a specific body area and causes heat in the tissues deep inside the skin for the treatment of specific disorders (pain, muscle spasm, joint contracture, etc.). The device is not used for the treatment of malignancies. Unlike surgical diathermy, the tissue is heated but not damaged.</td>
<td>11246000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
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</tr>
<tr>
<td>Ultrasound physical therapy system</td>
<td>An apparatus used for the relief of muscle pain. The device converts electromagnetic energy into ultrasonic waves that penetrate the target tissue and achieve pain relief by thermal and non-thermal physiological responses. The ultrasonic energy is transmitted via a special probe.</td>
<td>11248000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Ultrasonic bone growth stimulator</td>
<td>An apparatus that facilitates bone growth (osteoogenesis) by applying pulsed low-intensity ultrasound.</td>
<td>18154000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Canopy heating unit</strong></td>
<td>A device used to warm the whole body of a patient with radiant heat from above. The heat is provided to a specific area of the canopy. Therefore, warming can be controlled also with a control unit. It is usually used in a burn care unit or intensive care unit.</td>
<td>36855000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Canopy heating unit control unit</strong></td>
<td>A unit used for controlling the temperature of radiant heat generated in the canopy of the warming device and radiated.</td>
<td>36953000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Canopy heating unit system</strong></td>
<td>A system used for warming the body of a patient by providing controlled radiant heat. It consists of a canopy as the heat source and a control unit with heat control, heat monitoring and alarm functions.</td>
<td>37327000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Bath for hydro-massage therapy</strong></td>
<td>A bathtub equipped with catheter nozzles that emit a large amount of water jet for massage effect. The device is also called a non-invasive hydrotherapy unit. The device can be used for pain relief in patients with rheumatism, etc. The device is designed to be used</td>
<td>14450000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bath for arm</strong></td>
<td>A warm-bath apparatus for thermal therapy of the upper limbs. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water.</td>
<td>10182000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bath for leg</strong></td>
<td>A warm-bath apparatus for use in treatment of the lower limbs. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water.</td>
<td>12313000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bath for foot</strong></td>
<td>A warm-bath apparatus used in treating the feet. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water.</td>
<td>36557020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Bath for whole body</strong></td>
<td>A warm-bath apparatus used for thermal therapy of the upper/lower limbs or the whole body. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water.</td>
<td>36557020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Water pad heating control unit</strong></td>
<td>A unit that controls temperature and circulation of the liquid inside the water pad heating system. An antimicrobial agent(s) is usually added to the liquid used.</td>
<td>36956010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Water pad specific heating control unit</strong></td>
<td>A unit that controls temperature and circulation of the liquid inside a water pad heating system. Antibacterial agents are usually added to the liquid used. Devices that do not need maintenance management are excluded.</td>
<td>36956020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dry heating pad system</strong></td>
<td>A system used to warm the human body by heat generated from the power source. The device usually consists of a pad with an integrated thermogenic material/device such as heating wire or cable and a control unit for temperature control, monitoring, alerting, etc.</td>
<td>37329000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Water pad heating system</strong></td>
<td>A system used to warm the human body by circulation of heated water. The device consists of a pad in which warm water is circulated and a control unit for water heating/circulation, monitoring, and alerting, etc.</td>
<td>37330010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Water pad specific heating unit system</strong></td>
<td>A system used for warming the human body with preheated circulating water. This consists of pads in which heated water circulates, and a control unit which performs preheating and circulation of water, monitoring, and can set off an alarm. Devices that do not need maintenance management are excluded.</td>
<td>37330020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
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<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>UOM</td>
<td>Applicable 1</td>
<td>Applicable 2</td>
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<tr>
<td>Paraffin bath</td>
<td>An apparatus for relieving pain like arthralgia by immersing the patient's body part(s) such as hands and fingers in the bath filled with melted paraffin (wax) at a specified temperature.</td>
<td>35232000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Cold air therapy unit</td>
<td>A unit designed for treatment to relieve pain, etc. in patients with rheumatism, arthritis, neuralgia, etc. by cold air. The device delivers cold air to the area of inflammation or pain.</td>
<td>36758000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Cryogenic analgesia unit</td>
<td>A device used for obtaining analgesia (pain relief) by applying extremely low temperature (freezing temperature) to the body tissues. The device consists of a cryostat and a cooling probe, and may have a peripheral nerve block stimulator (nerve stimulator). It employs several methods, including a natural melting cycle, to protect tissues from permanent damage. Low-temperature analgesia is a therapy to block the peripheral nerves reversibly for a long period of time (several weeks or months) and is used post-operatively as well as</td>
<td>17140000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric pad heating unit</td>
<td>A pad electrically heated to warm the hypothermic patient. Both an adult size and a pediatric size are available. The device is usually used during prolonged surgery.</td>
<td>11989000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Perineal heating unit</td>
<td>A device that provides heat to the surface of perineum (the area between the vulva and the anus) by means of direct or indirect contact with the radiant heat source. It is useful for pain relief in the vulva after episiotomy (surgical incision of the vulva and the vagina to prevent laceration during delivery).</td>
<td>33594000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Water pad heating unit</td>
<td>A blanket or mattress used to warm or cool the body. It uses water for heat exchange. A pediatric size or an adult size may be available.</td>
<td>36854010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Water pad non-specific heating unit</td>
<td>A blanket or mattress for warming or cooling the body. Heat exchange is achieved using water. A pediatric size or an adult size may be available. Devices that require maintenance management are excluded.</td>
<td>36854020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Air pad heating unit</td>
<td>A blanket or mattress that can deliver warm air evenly, to offset normal body heat loss. It may cover the whole body or a part(s) of the body, may be designed for a specific body part, or may come in different sizes to suit the patient's build.</td>
<td>36931000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Air pad heating control unit</td>
<td>A device that filters room air, warms it to a preset temperature, and delivers it to the interior of a pad or blanket.</td>
<td>36954010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Control unit for air pad specific heating unit</td>
<td>A device that filters room air, warms it to a preset temperature, and delivers it to the interior of a pad or blanket. Equipment that requires no maintenance is excluded.</td>
<td>36954020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Applicable</td>
<td>Notes</td>
<td></td>
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<tr>
<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Electric pad heating control unit</td>
<td>A device for regulation/control of the temperature of an electrically heated pad.</td>
<td>36955000</td>
<td>II 9</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Insulating pad heating unit</td>
<td>A mattress that transforms itself in response to the characteristics of a patient body and completely alleviates pressure on the skin tissue. This device is made of insulating materials, and prevents temperature loss (hypothermia) by stopping any loss in body temperature.</td>
<td>37044000</td>
<td>II 9</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Air pad heating system</td>
<td>A system used to warm the human body with clean, heated air, to offset normal body heat loss. The device consists of a pad designed to receive warm air and a unit that controls air supply, heating, and monitoring, etc.</td>
<td>37328010</td>
<td>II 9</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Air pad specific heating system</td>
<td>A system used to warm the human body with clean, heated air, to offset normal body heat loss. The device consists of a pad designed to receive warm air and a unit that controls air supply, heating, and monitoring, etc. Equipment that requires no maintenance is excluded.</td>
<td>37328020</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Magnetic vibration heat therapy equipment</td>
<td>A system for heating the patient's body with the heat by the vibration and magnetism generated by a magnetic coil, etc. The device is composed of a component that delivers heat and a control unit for managing temperature, failure, etc.</td>
<td>70608000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Bed type massager</td>
<td>An electric device dedicated to be used on a bed or chair. The device may be integrated into a bed or chair and have additional features. The device massages someone lying on a bed or chair.</td>
<td>34488000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pneumatically-powered intermittent massager</td>
<td>A device used for non-invasive treatment of venous disorders. The device is used to apply counter pressure to the arms or the legs. The device is used to apply external pressure on the patient's arm or leg. Usually, the device is used for the treatment of leg edema. The device also allows for the treatment of cellulitis.</td>
<td>10969000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pneumatically-powered sequential massager</td>
<td>A device used for non-invasive treatment of venous disorders. The device facilitates venous blood flow by applying stimuli that stimulate muscle contraction. It is used to apply counter pressure to the arms or the legs. The device is a multiple-chamber device.</td>
<td>16837000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pneumatically-powered pressurizing massager</td>
<td>A device for non-invasive treatment of venous disease. The device is used with a dedicated compression unit. It exerts a counter pressure to the arms or the legs of a patient to improve blood circulation in the veins and imitates muscular activity. The device allows for the treatment of leg edema.</td>
<td>30877000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Pneumatically-powered massager with vibrating head</td>
<td>A hand-held pneumatic device that has a vibrating head mechanism and moves on the part of the body to be treated. The vibrating head (or pad) can be removed and exchanged for vibrating heads of various sizes and shapes. It is also used for stimulating and massaging the muscular structures of the body.</td>
<td>34489000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Plunger-like joint manipulator</td>
<td>A special plunger-like device used for joint manipulation and massage in chiropractic therapy.</td>
<td>33999000</td>
<td>II 9</td>
<td>applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Physiotherapy massager</td>
<td>An electric device (usually motorized) to provide an extensive range of effects in massage treatment. It utilizes a vibrating belt or other mechanism that comes into contact with the body. It is used for stimulating and massaging the muscular structures of the body or for treatment.</td>
<td>35538000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Joint/spinal manipulator</td>
<td>A special device used for the joint manipulation and massage in chiropractic therapy.</td>
<td>36229000</td>
<td>II 9</td>
<td>applicable</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Massager with vibrating head</td>
<td>A hand-held electric device that has a vibrating head (or a pad) and moves on the part of the body to be treated. The vibrating head can be removed and exchanged for vibrating heads of various sizes and shapes. It is also used for stimulating and massaging the muscular structures of the body. There are types used for respiratory and physical therapy.</td>
<td>36560000</td>
<td>II 9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Grade</td>
<td>Applicable</td>
<td>Other</td>
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</tr>
<tr>
<td><strong>Massager for ear drum</strong>&lt;br&gt;An electric device used in otolaryngological therapy to massage the tympanic membrane by air vibration. The device is usually composed of a crank and piston connected to a gear motor, the main unit, and bifurcated rubber tube that connects the main unit to the tympanic membrane.</td>
<td>70609000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Active extension/traction rotary motion equipment</strong>&lt;br&gt;An active device for training, reinforcement, and rehabilitation of muscles. Strength of muscles in the upper/lower limb, back, etc. is maintained, enhanced, and recovered.</td>
<td>70611000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active automatic traction unit</strong>&lt;br&gt;An active device used to widen the intervertebral space by applying tractional force on a body part (e.g., cervical spine or lumbar spine) with a harness worn on the head or at the pelvis. The device usually comprises a unit that controls tractional force, a motor, and a cord attached to the harness. An adjustable rod is used to change the angle of the cord.</td>
<td>14105002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active automatic intermittent traction unit</strong>&lt;br&gt;An active device that applies tractional force during traction therapy, in an intermittent or periodic manner according to the preset minimum/maximum force and duration.</td>
<td>14106002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active simplified traction unit</strong>&lt;br&gt;An active device that generates tractional (stationary) force during therapy.</td>
<td>35519002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active hand passive motion exerciser</strong>&lt;br&gt;An active device that realizes joint movement without exerting muscle power by continuously making the finger bend and stretch.</td>
<td>17137002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active lower extremity passive motion exerciser</strong>&lt;br&gt;An active device that realizes joint movement without exerting muscle power by continuously making the leg bend and stretch.</td>
<td>35977002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active upper limb passive motion exerciser</strong>&lt;br&gt;An active device that realizes joint movement without exerting muscle power by continuously making the arm bend and stretch.</td>
<td>35978002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Active respiratory exerciser</strong>&lt;br&gt;An active device that indicates respiratory volume or flow rate for a patient and improves ventilation by delivering a stimulus to the patient.</td>
<td>11634002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Single-use acupuncture needle</strong>&lt;br&gt;A single-use, elongated, pointed, unsterilized instrument that is used to stimulate peripheral nerves for anesthesia, pain relief, or other therapeutic effects.</td>
<td>35207002</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td><strong>Sterile acupuncture needle</strong>&lt;br&gt;A single-use, elongated, pointed, sterilized instrument that is used to stimulate peripheral nerves for anesthesia, pain relief, or other therapeutic effects.</td>
<td>34175000</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td><strong>Reusable contact needle</strong>&lt;br&gt;A device that stimulates the peripheral nerves through contact with the skin without insertion into the skin for surgical anesthesia, pain alleviation, or production of other treatment effects. This device is active and reusable.</td>
<td>70613002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td><strong>Acupuncture electrical stimulator</strong></td>
<td>A device used for electrical stimulation in acupuncture. The device consists of an apparatus for external stimulation and needle electrodes. Needle electrodes used for this device refer to single-use acupuncture needles.</td>
<td>13763000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Skin electrical conductivity measuring instrument</strong></td>
<td>An instrument used to measure conductivity of the patient’s skin based on skin thickness, moisture, electric conduction, etc.</td>
<td>31109000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Acupuncture kit</strong></td>
<td>A kit, tray or set of packaged devices or products used for acupuncture. It usually contains acupuncture needles and an acupuncture point detector.</td>
<td>10014000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electroshock electrode</strong></td>
<td>A conductor placed on a patient’s head in electroshock therapy for treatment of depression. It transmits electrical charges to the brain from the stimulator for electroconvulsive therapy.</td>
<td>11444000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Neuromuscular electrical stimulator for ejaculation</strong></td>
<td>A type of electrical neuromuscular stimulator used for stimulating the nerves that control the ejaculatory function. It is usually inserted into the rectum of a male patient. It consists of an electrode probe connected to an electrical pulse provider. It is used in male patients with neurological disorders to obtain sperm in assisted reproductive technology.</td>
<td>17912000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Transcutaneous peripheral nerve electrical stimulation electrode</strong></td>
<td>An electrode attached to the skin of a patient that provides electrical stimulation to reduce or resolve pain.</td>
<td>35995000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Electric potential therapy apparatus</strong></td>
<td>A device that generates an alternating current of hundreds to tens of thousands of volts or a continuous current of hundreds to about a thousand volts and applies it to the patient’s body, insulated from ground to achieve a holistic effect.</td>
<td>70614000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electrical stimulator for soft tissue</strong></td>
<td>An electrical stimulator that provides stimulation (usually, direct current) to damaged tissue from outside the body in order to promote cure.</td>
<td>35046000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electrical bone growth stimulator</strong></td>
<td>An apparatus that applies electric stimuli for bone growth (osteogenesis). The device is used as alternative to bone grafting, for the treatment of intractable (unknitted) fracture or as adjunctive therapy for spinal fusion. The device applies a weak electric current to the fracture or around the fusion site, or generates an electromagnetic field (to utilize an A device that sends gas or liquid (pigment for the tubal patency test) into the fallopian tubes (the tubes or oviducts leading from the ovary to the uterus or womb) to maintain the patency of the tubes.</td>
<td>35463000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Tubal patency insufflator</strong></td>
<td>A device that sends gas or liquid (pigment for the tubal patency test) into the fallopian tubes (the tubes or oviducts leading from the ovary to the uterus or womb) to maintain the patency of the tubes.</td>
<td>36772000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Hydrotubation instrument</strong></td>
<td>An operative device for performing hydrotubation using water or a drug solution (contrast media) during laparoscopic surgery in fertility treatment for diagnosis or treatment of tubal patency.</td>
<td>70616000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
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<table>
<thead>
<tr>
<th>Physical Therapy Equipment Type</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Application</th>
<th>Applicability</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavior therapy electrical stimulator</td>
<td>A type of stimulator used to provide an electrical impulse, harmless but uncomfortable, to a patient (the arm, leg, etc.) in order to correct undesirable behavioral characteristics. It is usually used in aversion therapy by a therapist or in aversion therapy under a home-based clinical treatment program. Some types may provide stimulation in conjunction and for treatment, a perfusion unit, a compressor, an electrical abrader. It is used for treatment of indurated skin, corns, ingrown nails, and other disorders of the leg.</td>
<td>34875000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Chiropody treatment unit</td>
<td>A unit that can be equipped with the functions of devices including aspirators for foot care and for treatment, a perfusion unit, a compressor, an electrical abrader. It is used for treatment of indurated skin, corns, ingrown nails, and other disorders of the leg.</td>
<td>37212000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Combined physical therapy equipment</td>
<td>A physiotherapy apparatus that integrates a massage bed, active automatic traction unit, etc. into one unit and enables the use of one feature without others. &quot;Active automatic traction unit, etc.&quot; refers to active automatic traction units, active automatic intermittent traction units, and active simplified traction units.</td>
<td>70618000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Constant current treatment unit</td>
<td>An apparatus that always applies a weak direct current to the human body through the skin at a constant amount by automatically adjusting the voltage according to the fluctuation in the biological impedance. The device is commonly used to get rid of or treat pain, etc.</td>
<td>70619000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Low frequency therapy equipment/interference low frequency therapy equipment</td>
<td>An apparatus that has functions of low frequency therapy equipment and interference low frequency therapy equipment. (See definitions of low frequency therapy equipment and interference low frequency therapy equipment.)</td>
<td>70620000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Low frequency therapy equipment/skin electrical conductivity measuring instrument</td>
<td>An apparatus that has functions of low frequency therapy equipment and skin electrical conductivity measuring instrument. (See definitions of low frequency therapy equipment and skin electrical conductivity measuring instrument.)</td>
<td>70621000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Low frequency therapy equipment/acupuncture electrical stimulator/skin electrical conductivity measuring instrument</td>
<td>An apparatus that has functions of low frequency therapy equipment, acupuncture electrical stimulator, and skin electrical conductivity measuring instrument. (See definitions of low frequency therapy equipment, acupuncture electrical stimulator, and skin electrical conductivity measuring instrument.)</td>
<td>70622000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Low frequency therapy equipment/ultrasound physical therapy system</td>
<td>An apparatus that has functions of low frequency therapy equipment and ultrasound physical therapy system. (See definitions of low frequency therapy equipment and ultrasound physical therapy system.)</td>
<td>70623000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Low frequency therapy equipment/interference low frequency therapy equipment/ultrasound physical therapy system</td>
<td>An apparatus that has functions of low frequency therapy equipment, interference low frequency therapy equipment, and ultrasound physical therapy system. (See definitions of low frequency therapy equipment, interference low frequency therapy equipment, and ultrasound physical therapy system.)</td>
<td>70624000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential therapy apparatus/infrared light therapy unit</td>
<td>An apparatus that has functions of electric potential therapy apparatus and infrared light therapy unit. (See definitions of electric potential therapy apparatus and infrared light therapy unit.)</td>
<td>70625000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
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</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Quantity</td>
<td>Applicable</td>
<td>Notes</td>
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</tr>
<tr>
<td>Ultraviolet light therapy unit/infrared light therapy unit combined physical therapy equipment</td>
<td>An apparatus that has functions of ultraviolet light therapy unit and infrared light therapy unit. (See definitions of ultraviolet light therapy unit and infrared light therapy unit.)</td>
<td>70626000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Low frequency therapy equipment/dry heating pad system combined physical therapy equipment</td>
<td>An apparatus that has functions of low frequency therapy equipment and dry heating pad system. (See definitions of low frequency therapy equipment and dry heating pad system.)</td>
<td>70627000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Low frequency therapy equipment/xenon beam light therapy unit combined physical therapy equipment</td>
<td>An apparatus that has functions of low frequency therapy equipment and xenon beam light therapy unit. (See definitions of low frequency therapy equipment and xenon beam light therapy unit.)</td>
<td>70628000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Water pad heating system/air pad heating system combined physical therapy equipment</td>
<td>An apparatus that has functions of water pad heating system and air pad heating system. (See the definitions of water pad heating system and air pad heating system).</td>
<td>70629000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Treatment electrosurgical plate</td>
<td>A relatively large electrode used to decrease the density of returning high-frequency current to a level that does not burn human tissue. The device is pasted on the patient’s body. The device comes with conductive cords and other accessories. The device is not intended for a specific treatment.</td>
<td>11500002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>General electrosurgical unit</td>
<td>A device accompanied by accessories that cuts/coagulates tissues with a high-frequency current or with the electricity/heat of the heating element. The device is used by a physician to confirm that an incision or coagulation is made as intended, macroscopically or microscopically. The device is not intended for a specific therapeutic effect.</td>
<td>70647000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Powered dermatome</td>
<td>An electric surgical device used for removal of the fragment of damaged skin or for thinly slicing the skin of a donor for skin graft. A dedicated blade should be used for these purposes.</td>
<td>11179000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Trephine system control unit</td>
<td>A part of the trephine system used to control the motorized trephine device when particular attention is required when adjusting the cutting speed in ophthalmic surgery including corneal transplantation. It is used for adjustment of the trephine speed (rpm).</td>
<td>43928000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Gas-powered trephine system</td>
<td>A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a gas-driven device.</td>
<td>32724000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Type</td>
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<td>Classification</td>
<td>Applicability</td>
<td>Notes</td>
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</tr>
<tr>
<td>Battery-powered trephine system</td>
<td>A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a battery-driven device.</td>
<td>32820000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Electrically-powered trephine system</td>
<td>A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard soft tissues, or soft tissues. It may have a speed control device. This is an AC-powered device.</td>
<td>32821000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Powered corneal trephine</td>
<td>An electric cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft.</td>
<td>14148022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Vitrectomy unit</td>
<td>An apparatus used in ophthalmic surgery for partial resection of the vitreous body. For example, the device may be used to control a cutter handpiece (usually with a vibrating blade) that sever excess tissue (piece by piece) and removes the cut pieces by gentle</td>
<td>14386000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Vitrectomy unit cutter handpiece</td>
<td>A device used with a base unit in ophthalmic surgery such as vitrectomy. For example, it may be a vibrating knife (nibbler) controlled by a base unit through a cable.</td>
<td>34125000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Bipolar electrode</td>
<td>A bipolar electrode, conductive cords, and accessories used for incision/coagulation of tissues with a high-frequency current. A bipolar electrode is made up of one supporting part equipped with two active electrodes between which a high-frequency current runs. A device intended for performing incision and coagulation of tissues by a physician under local anesthesia.</td>
<td>70655000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Automated percutaneous discectomy system</td>
<td>A system for automated, percutaneous removal of the nucleus pulposus from the intervertebral disc. The system enables single-step removal and suction of the nucleus pulposus without repeated Nucleotome insertion. The system is used as an alternative to discectomy. The system is usually operated under local anesthesia.</td>
<td>36077000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Hemostatic knife</td>
<td>A surgical severing instrument that is similar to a scalpel, excluding the fact that its blade is designed to be heated with an electric current. The blade transmits heat directly to body tissues to achieve hemostasis. The instrument uses thermal energy for the</td>
<td>36136000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable epilator tweezers electrode</td>
<td>A tweezer-type electrode used with an epilator. It is used to destroy the dermal hair papillae with an electric current supplied from the base unit to around the hair shaft for hair removal. This device is reusable.</td>
<td>37485000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable epilator needle electrode</td>
<td>A needle type electrode used with an epilator. It is used to destroy the dermal hair papillae with an electric current supplied from the base unit to around the hair shaft, and subcutaneous and dermal papillae for hair removal. This device is reusable.</td>
<td>38798000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>High-frequency current procedure active instrument</td>
<td>A set of instruments comprising an active electrode that incises/coagulates tissues with a high-frequency current, a probe that achieves incision/coagulation by the electricity/heat of the heater element, conductive cords, and other accessories. Sets used with an</td>
<td>70662000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
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<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Code</th>
<th>Subcode</th>
<th>Applicability</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-use catheter for rectal prostatic hypertrophy hyperthermia unit</td>
<td>A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia or a cooler for hyperthermia equipment for prostatic hyperplasia. A cooling medium (e.g., water) is provided from the main equipment or individual cooling unit to the catheter.</td>
<td>42454000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable catheter for microwave urethral prostatic hypertrophy hyperthermia unit</td>
<td>A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia. The catheter is inserted transurethrally. The surrounding sites and organs may need cooling during the treatment procedure.</td>
<td>36921000</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use catheter for microwave urethral prostatic hypertrophy hyperthermia unit</td>
<td>A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia. The catheter is inserted transurethrally.</td>
<td>42455010</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use high-frequency/radio-frequency urethral prostatic hypertrophy hyperthermia unit catheter</td>
<td>A dedicated information system consisting of computers and software. This uses the data related to diagnostic images (e.g., X-ray, CT scan, MRI, or two or three-dimensional images) obtained through virtual simulation using a positioning device for radiation therapy or the data related to specific radiation therapies (e.g., brachytherapy, remote radiation therapy, accelerator) and calculates the setting values and enters them in the computer.</td>
<td>42455020</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgical navigation unit</td>
<td>An apparatus that displays the location of instrument to assist the surgeon during stereotactic surgery. The device is based on computer technology and usually includes a console that is operated by the surgeon. There are other devices (e.g., a locating device) attached to it for tracking the instrument used. Input into the computer commonly consists of CT or MRI images or spatial coordinates and one type of such information.</td>
<td>38723002</td>
<td>II</td>
<td>6,7</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use dental root canal reamer</td>
<td>A hand-held rotary dental surgical instrument used to enlarge and clean the root canal by performing a lateral cut. The device is sterilized and intended for single-use.</td>
<td>31875012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental root canal reamer</td>
<td>A rotary dental surgical instrument connected to an active device to enlarge and clean the root canal by performing a lateral cut.</td>
<td>31875022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use dental file</td>
<td>A hand-held dental surgical instrument used to enlarge the root canal and smooth out the root canal wall by scratching/scraping with vertical reciprocating motion or plucking motion. The instrument is sterilized and intended for single-use.</td>
<td>31878012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental file</td>
<td>A dental instrument connected to active medical equipment to enlarge the root canal and smooth out the root canal wall by scratching/scraping with vertical reciprocating motion or plucking motion.</td>
<td>31878022</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered drill for dental use</td>
<td>A rotary tool connected to a dental drill handpiece. The device makes a hole in the tooth to fixate a ready-made or cast pin, which holds a restoration.</td>
<td>43311000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental drill system</td>
<td>An electrical dental drilling system consisting of a powered dental drill handpiece and a complete set of various attachments. The power source is electricity, gas pressure or remote drives. This device can be configured according to the purpose of use and used in conjunction with other devices.</td>
<td>44015000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental root canal orifice enlargement drill</td>
<td>A device connected to an active medical device to obtain access to and enlarge an opening of root canal.</td>
<td>70686000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental root canal filling paste remover</td>
<td>An electric dental instrument with a spiral/conical coil spring as a working tip for removal of the filling material inside a root canal.</td>
<td>70688000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental air-powered rotary unit</td>
<td>A device that runs equipment for cutting/polishing teeth, denture, dental crowns, etc. by compressed air. Dental gas-powered handpiece are excluded.</td>
<td>70689000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental electrically-powered rotary unit</td>
<td>An electric dental device that runs equipment for cutting/polishing teeth, denture, dental crowns, etc. Electrically-powered dental handpiece are excluded. The device may include instruments used for peeling/removal of prostheses, foreign bodies, etc. from the root canal.</td>
<td>70690000</td>
<td>II</td>
<td>5-⑥,9</td>
<td>applicable</td>
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<td>Description</td>
<td>SIT No</td>
<td>Class</td>
<td>CE</td>
<td>Date</td>
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<tr>
<td>Dental jet cutting instrument</td>
<td>A device that cuts teeth by blowing powder on them. The device is sometimes used for cleaning/polishing of teeth. The device comes with polishing powder.</td>
<td>70691000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental gas-powered handpiece</td>
<td>A surgical handpiece with a chuck to connect a rotary device such as dental burs and reamers. The device usually contains a small turbine powered by compressed air and a water spray for cooling the rotary grinding instrument. The device may be connected to an electrical motor.</td>
<td>40958000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrically-powered dental handpiece</td>
<td>An electrically-powered dental handpiece with a chuck used to connect a dental device, such as dental burs and reamers, which rotates, vibrates, repeats rotation, reciprocates, or moves in combination of these motions. The device has an integrated electric motor.</td>
<td>38347000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Straight and geared angle handpiece</td>
<td>A device driven by air-powered rotary unit, electrically-powered rotary unit, etc. for dental burs, reamers, etc. to rotate, vibrate, repeat rotation, reciprocate, or move in combination of these motions. The device may have a linear or angled shape.</td>
<td>70692000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental practice electric engine and related instrument</td>
<td>A dental device includes a dental electric motor, a motor stand, a belt for the motor, a bracket arm for the motor, and a K4 pulley used for dental treatment. Dental air-powered rotary unit and dental electrically-powered rotary unit are excluded.</td>
<td>70694000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental endodontic paste carrier</td>
<td>An electronical endodontic instrument with a spiral or conical coil-like spring on its working tip. The device is used to deliver filling materials and drugs to the root canal.</td>
<td>41539000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental multipurpose treatment motor</td>
<td>An electric dental drill handpiece capable of measuring the root canal length. It includes the battery-operated type.</td>
<td>70695000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental pulp testing electrical stimulator</td>
<td>An electrical dental pulp examiner, which applies a high-frequency current from its electrode to stimulate the nerve tissue of dental pulp for assessment of the pain reaction.</td>
<td>13187000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Endodontic apex locator</td>
<td>An electrical dental device to determine the location of the root canal tip for endodontic care.</td>
<td>16355000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental occlusal sound analyzer</td>
<td>A device that electrically measures occlusal sound (or vibration) generated by teeth contacts in chewing cycles. The device is used to test for premature contact that may cause occlusal interference.</td>
<td>70696000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Periodontal probe</td>
<td>A device that electrically measures the depth of periodontal pockets.</td>
<td>70697000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental mandibular movement analyzer</td>
<td>A device that electrically measures mandibular movement to detect abnormalities of the temporomandibular joint. The device may also be used for measurement of temporomandibular joint sounds or muscle action potentials</td>
<td>70698000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Optical calculus/plaque detector</td>
<td>A dental calculus/plaque detector. The device uses the optical property of calculus and plaque for detection.</td>
<td>33995010</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Optical caries detector</td>
<td>A dental caries detector. The device uses the optical property of caries for detection.</td>
<td>33995020</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric caries detector</td>
<td>A dental caries detector. The device uses the electrical property of caries for detection.</td>
<td>33995030</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Tooth mobility analyzer</td>
<td>A device that vibrates a tooth and electrically measures its mobility. The device can detect an abnormal load on a specific tooth or evaluate the severity of periodontal disease.</td>
<td>70701000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<td>Device Type</td>
<td>Description</td>
<td>Japanese Code</td>
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<td>Applying</td>
<td>T nostudy</td>
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<tr>
<td>Dental iontophoreser</td>
<td>An apparatus that introduces fluorine ion, etc. into the tooth substance using potential difference. The device is used for prevention of dental caries or treatment of root canal.</td>
<td>70703000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Rotary periodontal scaler</td>
<td>A power-driven device used for removal of deposits such as dental calculi from the tooth surface in dental cleaning and periodontal treatment. The oscillation type is included in this group.</td>
<td>31885000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic periodontal scaler</td>
<td>A powered device that uses an ultrasonic tip for removal of deposits (e.g., calculus) from the tooth surface in tooth cleaning or periodontic treatment.</td>
<td>36047000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Air-powered scaler</td>
<td>An air-powered device that, by mechanical vibration, removes deposits (e.g., calculus) from the tooth surface, enlarges the root canal, abrades teeth, or cleans periodontal tissue, etc. in tooth cleaning or periodontic treatment.</td>
<td>70704000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental endodontic enlarger</td>
<td>A device that has a sharply machined protrusion in the working part used to enlarge the root canal by grinding. It is driven by ultrasound waves or a dental handpiece that makes a rotatory or reciprocating motion.</td>
<td>40529000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Ultrasonic dental endodontic enlarger</td>
<td>An electrically powered device that enlarges the root canal by abrasion using the ultrasonic tip.</td>
<td>43076000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental endodontic enlarger</td>
<td>A device for enlarging and preparing the root canal, which probes, enlarges, and cleans the root canal by dental file, etc. The motion of the file includes vibrating, rotating, repeating rotation, reciprocating, and a combination of these motions.</td>
<td>70705000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental bilateral neuromuscular electrical stimulator</td>
<td>A device that applies electrical stimulation to relieve pain or relax muscles in the head/neck.</td>
<td>70706000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered tooth surface cleaner</td>
<td>A device that runs on external energy and is intended for cleaning and polishing the tooth surface by blowing powder mixed with water or air.</td>
<td>70707012</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Active device connected tooth surface cleaner</td>
<td>A device that blows powder mixed with water or air against the tooth surface for cleaning/polishing and is connected to an active medical device.</td>
<td>70707022</td>
<td>II</td>
<td>5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental tooth surface cleaner auxiliary material</td>
<td>Cleaning adjuvants used for a stained tooth surface after mechanical cleaning of the tooth surface. Products containing pharmaceutical ingredients are excluded.</td>
<td>70708000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental root canal irrigator</td>
<td>A device that cleans the root canal by mechanical vibration of an oscillator, etc.</td>
<td>70710000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Details</td>
<td>Code</td>
<td>Class</td>
<td>Quantity</td>
<td>Applicable</td>
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</tr>
<tr>
<td><strong>Root canal suction dryer</strong></td>
<td>A handpiece used to clear cutting debris and blood in the root canal by water flow, etc. and aspiration, and to dry the root canal by suction.</td>
<td>70711000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dental endodontic material electric heating injector</strong></td>
<td>A device used to inject gutta-percha, etc., which was previously heated/softened in the heating chamber attached to a handpiece, into the root canal. The device may run on battery.</td>
<td>70712009</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Active device dental root canal cleanser</strong></td>
<td>A device attached to a handpiece for removal of cutting debris from the root canal and for cleaning of the root canal wall. The device is attached to an active medical device.</td>
<td>70714002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Electrothermal endodontic plunger</strong></td>
<td>A dental device with a cylindrical or tapered working tip that is heated to melt and insert filling material. The device is commonly used to compress the filling material in the root canal in the direction of tooth axis.</td>
<td>70716000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Tooth bleach activation apparatus</strong></td>
<td>An optical or electrical heat source that activates a dental bleaching agent or drug-containing dental tooth surface cleaner auxiliary material for tooth surface cleaning applied on the tooth.</td>
<td>70717000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Chairside dental CAD/CAM unit</strong></td>
<td>An apparatus using a complex software system, installed in a clinic or a dental office. It is used for computer-aided design (CAD) or computer-aided manufacturing (CAM) of dental restorations.</td>
<td>38597000</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Ultrasonic instruments for multi-purpose treatment</strong></td>
<td>An ultrasonic apparatus used for multi-purposes, such as removal of calculi/plaque, root canal preparation (enlargement, washing, cleaning), filling with gutta-percha, and root canal length measurement.</td>
<td>70719000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dental unit</strong></td>
<td>A unit equipped with utilities used in ordinary dental treatment/procedures such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with the operating light. The device usually comes with a chair for the patient receiving examination or treatment.</td>
<td>34991010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Dental optional additive unit</strong></td>
<td>A dental unit into which optional devices are incorporated. It includes units used for orthodontic treatment, pediatric treatment, and preventive dental treatment. The optional devices incorporated into the unit include a photopolymerization irradiator for dental treatment, a microwave scalpel, and an ultrasonic scaler for periodontal treatment. Portable types are excluded.</td>
<td>34991020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Orthodontic supply unit</strong></td>
<td>A dental unit equipped with utilities used in ordinary orthodontic treatment such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon).</td>
<td>70723000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Pediatric dental unit</strong></td>
<td>A dental unit equipped with utilities used in ordinary pediatric dentistry such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with the operating light. The device usually comes with a chair for the patient receiving examination or treatment.</td>
<td>70724000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Prophylactic dental unit</strong></td>
<td>A dental unit equipped with utilities used in ordinary preventive dentistry such as water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with a compressed air unit and the operating light. The device usually comes with a chair for the patient receiving examination or treatment.</td>
<td>16692000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Portable dental unit</strong></td>
<td>A portable dental unit with integrated tools for suction and oral cavity cleaning. The device may be used in orthodontics, pediatric dentistry, or preventive dentistry. The device is portable.</td>
<td>70725000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Portable dental optional additive unit</strong></td>
<td>A portable dental unit in which optional devices are incorporated. It includes units used for orthodontic treatment, pediatric treatment, and preventive dental treatment. The optional devices incorporated into the unit include a photopolymerization irradiator for</td>
<td>70726000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Item Description</td>
<td>Code</td>
<td>Class</td>
<td>MDC</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Dental suction unit</td>
<td>A suction device specifically designed for dental use that can remove water, blood, saliva, and particles that may be present in the oral cavity during dental treatment/procedures and droplets scattered from the oral cavity. The device may be a stand-alone device with a suction pump or have an electrically powered shutter for suction control.</td>
<td>34859000</td>
<td>II</td>
<td>9</td>
<td>applicable, N/A</td>
</tr>
<tr>
<td>Dental suction unit pump</td>
<td>An electrically-powered dental suction pump used as the suction source of a dental suction system, dental treatment unit, etc.</td>
<td>70727000</td>
<td>II</td>
<td>9</td>
<td>applicable, N/A</td>
</tr>
<tr>
<td>Dental water line filter</td>
<td>A filter used for removal of foreign substances from dental water used in dental treatment.</td>
<td>70728000</td>
<td>II</td>
<td>3-①</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic wire</td>
<td>A wire component of an orthodontic appliance system, coming in varying sizes and grades. This wire is used to apply pressure to a tooth to alter its position.</td>
<td>16204000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic tube</td>
<td>A component of an orthodontic appliance system, used as an attachment holding a wire to maintain the desired tooth alignment.</td>
<td>31759000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic spring</td>
<td>A device used to generate orthodontic force as a part of an orthodontic system. The device is usually a coiled, thin, metallic wire.</td>
<td>31797000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic magnet</td>
<td>A small magnet used to assist orthodontic treatment with functional orthodontic appliances and to achieve aligned teeth using traction by enlargement of the palate, depression of molars, distal shift of molars, and forced eruption of impacted teeth.</td>
<td>37601000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic band</td>
<td>A metal band commonly made of stainless steel sheet and used to keep an orthodontic attachment in contact with the teeth. The attachment is (hard) soldered to the band. The band is shaped to conform exactly to the shape of the tooth and cemented to a desired position.</td>
<td>38734000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic lock</td>
<td>An appliance such as Gurin lock used to fix an orthodontic arch wire to a bracket.</td>
<td>38741000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic attachment</td>
<td>A precision device welded or soldered to a band or glued to the tooth or other instruments. This device is used in orthodontic treatment to strengthen orthodontic force. Brackets, tubes, buttons, eyeslets, casts, hooks and sheaths are included in this category.</td>
<td>41059000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic clasp</td>
<td>A removable elastic retainer that is a component of orthodontic appliances. The device may be manufactured from clasp wire or cast or ready-made/prefabricated alloy.</td>
<td>41068000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic archwire</td>
<td>A dental wire used with an orthodontic attachment. This wire is fixed to the crowns of 2 or more teeth to shift the teeth and guide them to a desired position.</td>
<td>41397000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic material kit</td>
<td>A kit made up of wire, attachment, etc. that comprise an orthodontic appliance system. Devices with drug-containing component(s) are excluded.</td>
<td>70729000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic teeth positioner</td>
<td>A plastic appliance shaped to conform to the corrected bite impression, which is used to prevent shifting of the teeth or to shift the teeth to its final position after removal of orthodontic appliances (prosthetics). The patient continually bites the appliance for</td>
<td>33592000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic resin material</td>
<td>A material deriving from silicone rubber, plastics, or resins used to make orthodontic appliances and occlusal splints. Dental occlusal splint material is excluded.</td>
<td>70730000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic elastomer</td>
<td>An elastic material in varying shapes (structures) such as small ring (for binding), chain-like, or filamentous. This material is used with a variety of other orthodontic appliances. Elastic bands (polymer or rubber bands or sutures) are used in orthodontics to alter the</td>
<td>38733000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable, –</td>
</tr>
<tr>
<td>Orthodontic appliance elastic material</td>
<td>An elastic material and auxiliary materials used to fabricate removable, orthodontic elastic appliances.</td>
<td>70731000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthodontic face bow</td>
<td>An appliance used concurrently for extraoral traction that places an anchor on the head or posterior neck. The device is an elongated metal arch wire inserted into the orthodontic appliance in the oral cavity and commonly used to shift the teeth or jawbone posteriorly or to keep it from shifting anteriorly.</td>
<td>40468000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthodontic ligation material</td>
<td>A wire that secures the orthodontic arch wire or other appliances to the bracket slot.</td>
<td>41677000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthodontic bite guidance</td>
<td>A removable functional appliance used for treatment of early malocclusion, etc. The patient places the device in the oral cavity for a designated hours per day for the treatment of malocclusion, deep overbite, open bite, overlap etc.</td>
<td>70732000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental lip bumper</td>
<td>An orthodontic appliance used to block the movement of the mandibular molar (etc.) with the force deriving from the lips.</td>
<td>70737000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term orthodontic oral mucosa protector</td>
<td>A covering material on an orthodontic appliance, used to reduce stimulation to the oral mucosa. It is intended for long-term use.</td>
<td>70738000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental plating kit</td>
<td>A kit that contains plating solutions and dental plating devices for dental use.</td>
<td>70761000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental noble metal foil</td>
<td>A foil made of precious metal (gold, silver, platinum, or palladium) and mainly used to manufacture crown restoration.</td>
<td>70762000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental direct gold filling material</td>
<td>A gilt, sintered gold powder, or a combination of both used for gold filling inside the oral cavity directly. The filling material is plugged by a hammer or filling instrument, and cold welding occurs through plugging.</td>
<td>11159000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental gold bullion</td>
<td>Gold bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70763000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental silver bullion</td>
<td>Silver bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70764000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental platinum bullion</td>
<td>Platinum bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70765000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental palladium bullion</td>
<td>Palladium bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70766000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting gold alloy</td>
<td>An alloy for casting in which the proportion of gold is not less than 65% and that of a combination of gold and platinum group metals is not less than 75%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70767000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Number</td>
<td>Status</td>
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<tr>
<td>Dental casting low carat gold alloy</td>
<td>An alloy for casting in which the proportion of a combination of gold and platinum group metals is not less than 25% and less than 75%. Dental casting gold-silver-palladium alloy and dental casting 14-carat gold alloy are excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70768000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting 14-carat gold alloy</td>
<td>An alloy for casting in which the proportion of gold is 58.33% to 60.00%. It is used for fabrication of dental restorations and appliances.</td>
<td>70769000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Noble metal materials for dental metal-ceramic restorations</td>
<td>An alloy for casting in which the proportion of either gold or platinum group metals is not less than 35%, or that of a combination of gold and platinum group metals is not less than 35%. It is used to fabricate dental metal-ceramic restorations.</td>
<td>70770000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought gold alloy</td>
<td>An alloy not intended for casting in which the proportion of gold is not less than 65%, and that of a combination of gold and platinum group metals is not less than 75%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70771000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought low gold content alloys</td>
<td>An alloy not intended for casting in which the proportion of a combination of gold and platinum group metals is not less than 25% and less than 75%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70772000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental gold alloy brazing materials</td>
<td>A hard soldering material in which the proportion of gold is not less than 30%, and that of a combination of gold and platinum group metals is not less than 35%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70773000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting gold-silver-palladium alloy</td>
<td>An alloy for casting in which the proportion of gold is not less than 12%, that of palladium is not less than 20%, and that of silver is not less than 40%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70774000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought gold-silver-palladium alloy</td>
<td>An alloy not intended for casting and having a form of wire, plate, bar, or cap. The proportion of gold in this alloy is not less than 12%, that of palladium is not less than 25%, and that of silver is not less than 40%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70775000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental gold-silver-palladium alloy solders</td>
<td>A hard soldering material in which the proportion of gold is not less than 15%, that of a combination of gold and palladium is not less than 30%, and that of silver is not less than 30%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70776000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting silver alloy type 1</td>
<td>An alloy for casting free of gold and platinum group metals. The proportion of silver in this alloy is not less than 60% and that of indium is less than 5%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70777000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting silver alloy type 2</td>
<td>An alloy for casting free of gold. The proportion of silver in this alloy is not less than 60%, that of indium is not less than 5%, and that of platinum group metals is not more than 10%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70778000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental silver alloy brazing materials</td>
<td>A hard soldering material in which the proportion of silver is not less than 35%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70779000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Plus metal for dental casting 14-carat gold alloy</td>
<td>An alloy added to gold bullion for fabrication of dental casting 14-carat gold alloy. It is used for fabrication of dental restorations and appliances.</td>
<td>70780000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Plus metal for dental casting gold alloys</td>
<td>An alloy added to gold bullion for fabrication of dental casting gold alloy. Plus metals for dental casting 14-carat gold alloys are excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70781000</td>
<td>II</td>
<td>8①</td>
<td>applicable</td>
</tr>
<tr>
<td>Product Description</td>
<td>Description</td>
<td>Code</td>
<td>SIC</td>
<td>Status</td>
<td>Applyable</td>
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</tr>
<tr>
<td>Dental silver-palladium alloy solders</td>
<td>A hard soldering material primarily composed of silver and palladium. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70782000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting nickel-chromium alloy</td>
<td>An alloy for casting in which the proportion of a combination of nickel and chromium is not less than 50%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70783000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Nickel-chromium alloy wires for dental use</td>
<td>A wire-shaped alloy not intended for casting. The proportion of nickel in this alloy is not less than 70%, that of chromium is not less than 7%, and that of copper is not more than 7%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70784000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought nickel-chromium alloy plate</td>
<td>A plate shaped alloy not intended for casting. The proportion of nickel in this alloy is not less than 80%, that of chromium is not less than 5%, and that of copper is not more than 7%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70785000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought nickel-chromium alloy</td>
<td>An alloy not intended for casting primarily composed of nickel and chromium. Dental nickel-chromium alloy wire and dental nickel-chromium alloy plate are excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70786000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental nickel-chromium alloy solder</td>
<td>A hard soldering material primarily composed of nickel and chromium. It is mainly used in fabrication of dental restorations and appliances made from dental nickel-chromium alloy, dental stainless steel wire, dental cobalt-chromium alloy, etc.</td>
<td>70787000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting cobalt-chromium alloy</td>
<td>An alloy for casting in which the proportion of cobalt is not less than 40% and that of chromium is not less than 20%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70788000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought cobalt-chromium alloy wire</td>
<td>A wire-shaped alloy not intended for casting with the following compositions: for clasps and orthodontic appliances, cobalt, not less than 25%, chromium, not less than 15%; for burs, cobalt, not less than 20%, chromium, not less than 15%. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70789000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought cobalt-chromium alloys</td>
<td>An alloy not intended for casting and primarily composed of cobalt and chromium. Dental cobalt-chromium alloy wire is excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70790000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cobalt-chromium alloy solder</td>
<td>A hard soldering material primarily composed of cobalt and chromium. It is mainly used in fabrication of dental restorations and appliances made from dental nickel-chromium alloy, dental stainless steel wire, dental cobalt-chromium alloy, etc.</td>
<td>70791000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental stainless steel wire</td>
<td>A stainless steel wire used to fabricate dental clasps, burs, dowels, and orthodontic appliances.</td>
<td>70792000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental stainless steel alloy</td>
<td>A dental stainless alloy processed with dental stainless alloy plate or dental stainless steel wire. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70793000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting titanium alloy</td>
<td>An alloy for casting composed of pure titanium or primarily composed of titanium. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70794000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought titanium alloys</td>
<td>An alloy not intended for casting and composed of pure titanium or primarily composed of titanium. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70795000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Alloys for dental amalgam</td>
<td>A particulate alloy primarily composed of silver, tin, and copper. It is mixed with mercury to form dental amalgam. This alloy is in powder or tablet form, or comes in a capsule in which known amounts of the alloy and mercury are sealed by the manufacturer</td>
<td>34836000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Material</td>
<td>Description</td>
<td>Code</td>
<td>Tariff</td>
<td>Status</td>
<td>Application</td>
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<tr>
<td>Dental mercury</td>
<td>A high-purity mercury used as a component of dental amalgam for restoration of caries or fractured teeth.</td>
<td>35767000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental gallium alloy filling material</td>
<td>A filling material made of liquid gallium-tin-indium alloy. It turns into paste when mixed with a suitable alloy powder and hardens in the oral cavity.</td>
<td>38762000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Base metal materials for dental metal-ceramic restorations</td>
<td>A metal material used in dental metal-ceramic restoration, excluding metals of noble metal materials for dental metal/ceramic restorations. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70796000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental wrought alloys</td>
<td>A metal material not intended for casting and provided in various shapes, sizes, and materials. Metals identified elsewhere are excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70797000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental casting alloy</td>
<td>An alloy for casting used for fabrication of dental restorations and appliances. Metals identified elsewhere are excluded.</td>
<td>70798000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental brazing alloy</td>
<td>A hard soldering material used for dental cast restorations. Metals identified elsewhere are excluded. It is mainly used for fabrication of dental restorations and appliances.</td>
<td>70799000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental soldering material</td>
<td>A material suitable for soldering of dental cast restorations. It is a soluble alloy used for low temperature soldering of materials hard to melt (metal, wire, etc.).</td>
<td>38779000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ceramic tooth</td>
<td>A ready-made, ceramic (dental porcelain) prosthetic tooth mounted on a removable or fixed denture. It normally comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes.</td>
<td>38644000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental porcelain</td>
<td>A porcelain firing for fabrication of dental restorations such as inlays, prosthetic teeth, crowns, and bridges. It comes as a powder or paste. Dental metal/ceramic restoration porcelain is excluded.</td>
<td>70801000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental ceramic fused to metal restorative materials</td>
<td>A porcelain applied on a metallic crown frame and fired for fabrication of dental metal-ceramic restorations. It comes as a powder or paste.</td>
<td>70802000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental pressable ceramic</td>
<td>A dental porcelain molded by compression to fabricate dental restorations such as inlays, artificial teeth, crowns, and bridges.</td>
<td>70806020</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental injectable ceramic</td>
<td>A dental porcelain fabricated by injection molding and firing to fabricate dental restorations such as inlays, artificial teeth, crowns, and bridges.</td>
<td>70804000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental porcelain for machinable ceramic block</td>
<td>A ceramic block machined by a dental CAD/CAM unit to fabricate dental restorations such as inlays, prosthetic teeth, crowns, and bridges.</td>
<td>70805000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental porcelain kit</td>
<td>A kit composed of ceramic materials (porcelain dental ceramic, dental metal/ceramic restoration porcelain, dental casting ceramic, dental injection molding ceramic, and dental machinable ceramic block) and related appliances.</td>
<td>70806010</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
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<td>Category</td>
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<td>HS Code</td>
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</tr>
<tr>
<td>Acrylic resin tooth</td>
<td>A ready-made artificial tooth composed of acrylic resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and colors.</td>
<td>70807000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Synthetic hard resin tooth</td>
<td>A ready-made artificial tooth, made of hard resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and colors.</td>
<td>70808000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental molded temporary crown</td>
<td>An artificial crown commonly made of stainless steel, aluminum, or resin. It is placed over a damaged tooth or abutment tooth for temporary protective restoration.</td>
<td>34976000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
</tr>
<tr>
<td>Thermoplastic resin tooth</td>
<td>A ready-made artificial tooth made of thermoplastic resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and colors.</td>
<td>70809000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Metal cusp molar</td>
<td>An artificial posterior tooth with metal blade (metal cusp and occlusal surface) and resin body. The metal blade and resin components may be integrated or separate.</td>
<td>70810010</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Separable resin molar</td>
<td>An artificial tooth made of resin and separable into occlusal and base components. The separate occlusal component can be used as a casting pattern.</td>
<td>70810020</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental acrylic resins for crown and bridge</td>
<td>A material primarily made of methacrylate ester monomer and polymer, etc. and used for restoration of crowns and fabrication of temporary veneer crowns, etc. under various polymerization conditions.</td>
<td>70811010</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental synthetic resins for crown and bridge</td>
<td>A type of resin (harder than dental acrylic resin for crown and bridge) in powder, liquid, or paste containing at least one of methacrylate monomer, methacrylate polymer, inorganic filler and composite filler. This material is used for restoration of crowns and fabrication of temporary prosthetic appliances such as crowns and bridges that are used until permanent restorations are placed.</td>
<td>70811020</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Temporary dental polymeric crown/bridge</td>
<td>A material made of polymethylmethacrylate, etc. for fabrication of temporary prosthetic crowns, inlays, or temporary veneer crowns by injection molding, etc.</td>
<td>31783000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Crown/bridge thermoplastic resin</td>
<td>A thermoplastic material used to fabricate crowns, inlays, or temporary veneer crowns by injection molding.</td>
<td>70811030</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cusp</td>
<td>A material used to fabricate a cusp on the occlusal surface for improved occlusion.</td>
<td>16464000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Accessories for dental synthetic resins for crown and bridge</td>
<td>Accessories used to fabricate dental laboratory items with dental synthetic resins for crown and bridge.</td>
<td>70812000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Kit for dental synthetic resins for crown and bridge</td>
<td>A kit composed of dental synthetic resins for crown and bridge, building up tools, abrasive, and other related appliances.</td>
<td>70813000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental polymer-based crown/bridge staining material</td>
<td>A resin-based coloring material, etc. used to harmonize the color of polymer-based dental crowns with that of natural teeth.</td>
<td>70814000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental ceramics adhesive</td>
<td>A material used to bond a dental restorations (made of dental porcelain, ceramic, or resin-based material containing inorganic filler) or appliance to a resin-based material.</td>
<td>70815000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental resin adhesive</td>
<td>A material used to bond a resin-based prosthetic appliance or orthodontic bracket.</td>
<td>70816000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental tooth splint</td>
<td>A reinforcing material used for stabilization of a loose tooth or retention of orthodontic appliances, etc.</td>
<td>70817000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Repair kit for dental synthetic resins for crown and bridge</td>
<td>A kit used for color adjustment or repair of crown restorations made of dental synthetic resins for crown and bridge or dental acrylic resins for crown and bridge. It is a repair kit used for color adjustment or repair of crown restorations made of dental synthetic resins.</td>
<td>70818000</td>
<td>II</td>
<td>8-⑤</td>
<td>applicable</td>
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</tr>
<tr>
<td>Dental implant suprastructure</td>
<td>A dental prosthetic appliance to be secured to an abutment protruding from an implant and its retainer.</td>
<td>70819000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental inlay kit</td>
<td>A kit that contains combinations of a ready-made prosthesis or restoration, a chip for formation, an etching material, a bonding agent, dental composite resin for restoration</td>
<td>70820000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental machinable resin block</td>
<td>A resin-based block to be machined using a dental CAD/CAM unit to fabricate dental restorations such as inlays, prosthetic teeth, crowns, and bridges.</td>
<td>70821000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental preformed crown</td>
<td>A ready-made, artificial preformed crown commonly made of stainless steel, aluminum, or resin. Crowns designed for temporary use are excluded.</td>
<td>70822000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental ceramics staining material</td>
<td>A material used for color adjustment of dental ceramic materials.</td>
<td>70823000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Acrylic denture base resins</td>
<td>A material primarily made of methacrylate ester monomer and polymer, etc. and used for fabrication of a denture base under various polymerization conditions.</td>
<td>70824000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Denture base thermoplastic resin</td>
<td>A thermoplastic material used to fabricate denture bases, trial denture, bite plates, individualized trays, night guards, splints, etc. by injection, mechanical compression, air compression, or suction molding, etc.</td>
<td>70825000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Short-term soft lining materials for removable dentures</td>
<td>A soft lining elastic relining material for denture base designed for short-term use.</td>
<td>34769000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Long-term soft lining materials for removable dentures</td>
<td>A soft lining elastic relining material for denture base designed for long-term use.</td>
<td>34770000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental resin surface glazing/hardening material</td>
<td>A material applied to the surface of a resin-based prosthetic appliance. After hardening, this material enhances lubrication and abrasion resistance of the surface.</td>
<td>70826000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Denture base soft reliner</td>
<td>A relining material for denture base which remains soft after hardening.</td>
<td>17610000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Denture base resin accessories</td>
<td>Materials used to fabricate dental laboratory items with resin for a denture base.</td>
<td>70827000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Temporary denture base resin</td>
<td>A type of resin used to fabricate duplicate dentures, temporary dentures, etc.</td>
<td>70828000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Denture base reliner kit</td>
<td>A kit of materials used to reline/rebase a denture base or repair a broken denture base under various polymerization conditions.</td>
<td>70829000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
</tr>
<tr>
<td>Product Description</td>
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<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Denture base soft resin - A soft resin material used for a part of denture base for patients with cleft palate.</td>
<td>70830000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Denture repair kit - A kit containing materials necessary for repairing cracks or chips of denture. It usually comes with resin/bonding material, a mixing jar, and an applicator.</td>
<td>11171000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Denture base hard relining materials - A relining material for denture base which turns hard after hardening.</td>
<td>17609000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Denture base relining/rebase/repair resin - A type of resin used to reline/rebase a denture base or repair a broken denture base under various polymerization conditions.</td>
<td>70831000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Denture base adhesive - A bonding material used for fabrication/repair of denture bases. It is also called resin primer, denture primer, etc.</td>
<td>70834000</td>
<td>II</td>
<td>5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental zinc phosphate cement - A material that cures by a reaction between oxide powder (primarily zinc oxide) and phosphoric acid aqueous solution (may contain metal ions). It is used as a cementing agent to keep a dental prosthetic appliance in touch with hard tissue of oral cavity or</td>
<td>16710002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental silicophosphate cement - A material that cures by a reaction between powder of acid-degradable aluminosilicate glass and metal oxide (primarily zinc oxide) and phosphoric acid aqueous solution (may</td>
<td>16708000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental zinc polycarboxylate cements - A type of cement that cures by a reaction between zinc oxide and an aqueous solution of polycarboxylic acid or of similar polycarboxylic compound, or from a reaction induced by mixing a powder of zinc oxide and polycarboxylic acid with water. It is used as a</td>
<td>16705002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental resin-modified cement for denture reliner - A material primarily made of plain resin or resin containing inorganic powder and used for bonding a prosthetic appliance, tooth, etc. It may include a dental dentin adhesive, dental etching material, etc. Ones containing drugs are excluded.</td>
<td>70836002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental composite resin-modified cement - A cementing material for prosthetic appliances, etc. primarily made of plain resin or resin containing inorganic powder and not adhering to the tooth substance. Ones containing drugs are excluded.</td>
<td>70837002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental zinc oxide eugenol cement - A hydrophobic material containing eugenol that reacts with zinc oxide, an accelerator of the reaction, rubber, resin, and an inactive inorganic filler. It is used for temporary cementation, cementation, temporary restoration, lining, relining, or temporary sealing. Ones containing drugs are excluded.</td>
<td>16709002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental composite resin-modified cement - A lining/capping cement primarily composed of aluminum hydroxide powder and polycarboxylic acid aqueous solution.</td>
<td>70840000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
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<td>Description</td>
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<tr>
<td>Dental resin-modified glass-polyalkenoate luting cement</td>
<td>A cementing and bonding material used for dental restorations, prosthetic appliances, and orthodontic appliances. It is a combination of a resin component and glass polyalkenoate cement for dental cementation. Ones containing drugs are excluded.</td>
<td>70841002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cement kit</td>
<td>A kit consist of dental cement and other appliances, etc. that are used for mixing and condensation. Kits with drug-containing components are excluded.</td>
<td>70842000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cyanoacrylate cement</td>
<td>A cementing and bonding material primarily composed of cyanoacrylate monomer and used for dental prosthetic appliances.</td>
<td>70843000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental colour matching test material</td>
<td>A material used to examine the color compatibility of restorations, etc. with the teeth.</td>
<td>70844000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental trial colour matching test material</td>
<td>A try-in material used for color compatibility assessment of dental cement.</td>
<td>70845000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental loose teeth fixation adhesive</td>
<td>A resin-based bonding material used to fix a loose tooth, etc. Ones containing drugs are excluded.</td>
<td>70846000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental restorative composite resin kit</td>
<td>A package containing composite resin materials for dental fillings polymerized by mechanical mixing, by hand mixing, or by external energy. The materials are mainly for direct or indirect restoration of a tooth cavity.</td>
<td>35876000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental composite resins for restoration</td>
<td>Materials primarily composed of resin, inorganic filler or resin and composite filler. They are polymerized chemically by mixing or by external energy. They are used for filling of a tooth cavity or repair of artificial crowns. Drug containing materials are excluded.</td>
<td>70847002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Polymer-based bracket adhesive and tooth conditioner</td>
<td>A bracket bonding resin/tooth conditioner is a bonding material made of polymethylmethacrylate, etc. used to cement an orthodontic bracket to the tooth surface. Ones containing drugs are excluded.</td>
<td>31750002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental polymer-based adhesive</td>
<td>A filler-free resin used to support mechanical adhesion of a composite restorative material to acid-treated enamel.</td>
<td>34782000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental etching material</td>
<td>An acid aqueous solution or a gelled acid used to treat the adherend surface for sustained adhesion of composite resin, bonding material, or pit and fissure sealant.</td>
<td>36153000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental dentin adhesive</td>
<td>A filling material used primarily to facilitate adhesion of composite resins, restorations, or bonding material to dentin. It may also be used as a bonding material for enamel. Ones containing drugs are excluded.</td>
<td>42483002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental filling glass polyalkenoate cement</td>
<td>A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It is used for tooth filling and restoration. Ones containing drugs are excluded.</td>
<td>70848002</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental core build-up glass polyalkenoate cement</td>
<td>A type of cement that cures by a reaction of either aluminosilicate glass powder or a powder of melted glass and metal with alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It may contain metal powder. It is used for core build-up. Drug containing materials are excluded.</td>
<td>70849012</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Material Type</td>
<td>Description</td>
<td>Drug Containing Materials Excluded</td>
<td>Kanto region applicable</td>
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</tr>
<tr>
<td>Dental core build-up resin-modified glass-polyalkenoate cement</td>
<td>A cement material composed of a resin component and a glass polyalkenoate cement for core build-up. Drug containing materials are excluded.</td>
<td>70849022 II 8-① applicable</td>
<td>—</td>
<td></td>
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</tr>
<tr>
<td>Dental lining/basing glass polyalkenoate cement</td>
<td>A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It is used for lining or relining. Drug containing materials are excluded.</td>
<td>70850002 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental silicate cement</td>
<td>A material that cures by a reaction between aluminosilicate glass powder and phosphoric acid aqueous solution (may contain metal ions). It is used for esthetic restoration of frontal teeth. Drug containing materials are excluded.</td>
<td>34784000 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polymer-based pit and fissure sealants</td>
<td>A resin material suitable for sealing dental pits and fissures. It cures by chemical polymerization or polymerization by external energy. Ones containing drugs are excluded.</td>
<td>31780002 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental pit/fissure sealing glass polyalkenoate-based cement</td>
<td>A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It may contain resin components. It is used for sealing dental pits and fissures. Ones containing drugs are excluded.</td>
<td>70851012 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental pit/fissure sealing resin-modified glass-polyalkenoate cement</td>
<td>A dental pit and fissure sealant composed of a resin component and glass polyalkenoate cement for pit and fissure sealing. Ones containing drugs are excluded.</td>
<td>70851022 II 8-① applicable</td>
<td>—</td>
<td></td>
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</tr>
<tr>
<td>Dental glazing/hardening material</td>
<td>A dental glazing/hardening material is intended to smooth out and glaze the surface of a restorative filling material.</td>
<td>34771000 II 8-① applicable</td>
<td>—</td>
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<td></td>
</tr>
<tr>
<td>Dental ceramic repair kit</td>
<td>A pre-packaged kit for repair of broken ceramic restorations or prosthetic appliances. The kit includes etching gel/solution, bonding material, silane-based solution, polymer restorative (composite) material, and other accessories.</td>
<td>35877000 II 8-① applicable</td>
<td>—</td>
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</tr>
<tr>
<td>Dental pulp-capping material</td>
<td>Materials of various compositions used for capping deep cavities. Materials intended for absorptivity or biological effects, or containing drugs or biological raw materials are excluded.</td>
<td>38770000 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material for dental core build-up</td>
<td>A polymeric material used for core build-up on the root canal post.</td>
<td>38789000 II 8-① applicable</td>
<td>—</td>
<td></td>
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</tr>
<tr>
<td>Dental filling material kit</td>
<td>A dental restoration kit containing dental composite resins for restoration, an etching material, bonding material, etc. Those with drug-containing components are excluded.</td>
<td>70853002 II 8-① applicable</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental filling resin-modified glass-polyalkenoate cement</td>
<td>A dental filling material composed of a resin component and glass polyalkenoate cement for dental filling material. It may be used in the repair of artificial crowns. Ones containing drugs are excluded.</td>
<td>70854002 II 8-① applicable</td>
<td>—</td>
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<td></td>
</tr>
<tr>
<td>Dental composite resins for indirect restoration</td>
<td>A material composed primarily of resin and inorganic filler or of composite filler and polymerized by external energy. A crown, inlay, etc. is fabricated on a tooth with a cavity or on a model of the tooth and polymerized to fabricate a restoration. Ones containing polyalkenoate cement for dental filling material.</td>
<td>70855002 II 8-① applicable</td>
<td>—</td>
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</tr>
<tr>
<td>Dental filling acrylic resin</td>
<td>A material made primarily of acrylic ester monomer and polymer. It is polymerized chemically by mixing or by external energy. It is mainly used for filling of a tooth cavity or repair of artificial crowns. Drug containing materials are excluded.</td>
<td>70856000 II 8-① applicable</td>
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</tr>
<tr>
<td>Dental polymer-based restoratives modifier</td>
<td>A material used to adjust the viscosity or color of resin-based dental filler.</td>
<td>70857000 II 8-① applicable</td>
<td>—</td>
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</tr>
<tr>
<td>Dental adhesive/filling material surface hardening protection material</td>
<td>A material used to facilitate curing of the surface of dental resin-based cement, glass polyalkenoate cement for dental filling, or dental composite resins for restoration. This material is also used for protection of such surface.</td>
<td>70858000 II 8-① applicable</td>
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<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Section</td>
<td>Subsection</td>
<td>Applicable?</td>
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<tr>
<td>Tooth surface conditioning material A material used to process the tooth</td>
<td>Tooth surface conditioning material A material used to process the tooth</td>
<td>70859000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>surface after cavity or root canal preparation. Materials with absorptivity</td>
<td>surface after cavity or root canal preparation. Materials with absorptivity</td>
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<tr>
<td>or biological effects, or containing drugs or biological raw materials are</td>
<td>or biological effects, or containing drugs or biological raw materials are</td>
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<td>excluded.</td>
<td>excluded.</td>
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<tr>
<td>Dental sealing/coating material A material used to seal the dentinal tubule</td>
<td>Dental sealing/coating material A material used to seal the dentinal tubule</td>
<td>70860000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>or cavity margin. It is applied on the surface or interface of the tooth</td>
<td>or cavity margin. It is applied on the surface or interface of the tooth</td>
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<tr>
<td>substance, restorative filling material, prosthetic appliances, etc.</td>
<td>substance, restorative filling material, prosthetic appliances, etc.</td>
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</tr>
<tr>
<td>Tooth surface coating material A low-viscosity resin-based material for</td>
<td>Tooth surface coating material A low-viscosity resin-based material for</td>
<td>70861002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>coating of tooth surface. It may be included in a kit containing other</td>
<td>coating of tooth surface. It may be included in a kit containing other</td>
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<tr>
<td>materials. Ones containing drugs are excluded.</td>
<td>materials. Ones containing drugs are excluded.</td>
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<tr>
<td>Dental polymer-based cavity lining/basing material A polymer-based lining</td>
<td>Dental polymer-based cavity lining/basing material A polymer-based lining</td>
<td>70863002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>material such as glass polyalkenoate resin cement. Ones containing drugs</td>
<td>material such as glass polyalkenoate resin cement. Ones containing drugs</td>
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<td>are excluded.</td>
<td>are excluded.</td>
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<tr>
<td>Dental composite resin kit for indirect restoration A kit containing</td>
<td>Dental composite resin kit for indirect restoration A kit containing</td>
<td>70864002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>composite resin for dental indirect restoration, dental cement used together</td>
<td>composite resin for dental indirect restoration, dental cement used together</td>
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<tr>
<td>with a composite resin, and other related substances such as etching</td>
<td>with a composite resin, and other related substances such as etching</td>
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<tr>
<td>materials.</td>
<td>materials.</td>
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</tr>
<tr>
<td>Dental core build-up material A dental restoration kit containing material</td>
<td>Dental core build-up material A dental restoration kit containing material</td>
<td>70865002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>for dental core build-up, a dental etching material, and dental dentin</td>
<td>for dental core build-up, a dental etching material, and dental dentin</td>
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<tr>
<td>adhesive, etc. Kits with drug-containing components are excluded.</td>
<td>adhesive, etc. Kits with drug-containing components are excluded.</td>
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<tr>
<td>Dental dentin adhesive kit A kit containing a dental dentin adhesive and</td>
<td>Dental dentin adhesive kit A kit containing a dental dentin adhesive and</td>
<td>70866002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>a dental etching material. It may contain other appliances. Kits with drug-</td>
<td>a dental etching material. It may contain other appliances. Kits with drug-</td>
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<tr>
<td>containing components are excluded.</td>
<td>containing components are excluded.</td>
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<tr>
<td>Dental temporary stopping A temporary sealant composed primarily of polymeric</td>
<td>Dental temporary stopping A temporary sealant composed primarily of polymeric</td>
<td>70867000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
</tr>
<tr>
<td>material (such as gutta-percha), wax, zinc oxide, etc.</td>
<td>material (such as gutta-percha), wax, zinc oxide, etc.</td>
<td></td>
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</tr>
<tr>
<td>Dental zinc oxide eugenol temporary sealing material A temporary sealant</td>
<td>Dental zinc oxide eugenol temporary sealing material A temporary sealant</td>
<td>70868000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>primarily made of zinc oxide and eugenol.</td>
<td>primarily made of zinc oxide and eugenol.</td>
<td></td>
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</tr>
<tr>
<td>Dental temporary sealing material kit A kit made up of dental temporary</td>
<td>Dental temporary sealing material kit A kit made up of dental temporary</td>
<td>70869000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>sealants and related appliances. Kits with drug-containing components are</td>
<td>sealants and related appliances. Kits with drug-containing components are</td>
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<tr>
<td>excluded.</td>
<td>excluded.</td>
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<tr>
<td>Dental polymer-based temporary sealing material A temporary sealant</td>
<td>Dental polymer-based temporary sealing material A temporary sealant</td>
<td>70870002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>composed primarily of polymeric material. Ones containing drugs are</td>
<td>composed primarily of polymeric material. Ones containing drugs are</td>
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<tr>
<td>excluded.</td>
<td>excluded.</td>
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</tr>
<tr>
<td>Dental temporary sealing material Materials used for temporary sealing.</td>
<td>Dental temporary sealing material Materials used for temporary sealing.</td>
<td>70871002</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Materials identified elsewhere or containing drugs are excluded.</td>
<td>Materials identified elsewhere or containing drugs are excluded.</td>
<td></td>
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</tr>
<tr>
<td>Dental periodontal dressing A paste material usually applied around</td>
<td>Dental periodontal dressing A paste material usually applied around</td>
<td>35573000</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
</tr>
<tr>
<td>periodontal tissue for covering and protection after surgery. Materials</td>
<td>periodontal tissue for covering and protection after surgery. Materials</td>
<td></td>
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</tr>
<tr>
<td>intended for absorptivity or biological effects, or containing drugs or</td>
<td>intended for absorptivity or biological effects, or containing drugs or</td>
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</tr>
<tr>
<td>biological raw materials are excluded.</td>
<td>biological raw materials are excluded.</td>
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</tr>
<tr>
<td>Dental gutta-percha points A material made from sap condensate of certain</td>
<td>Dental gutta-percha points A material made from sap condensate of certain</td>
<td>31872000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>tropical tree and used as root canal filling. Gutta-percha softens on</td>
<td>tropical tree and used as root canal filling. Gutta-percha softens on</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>heating and cures on cooling after filled in a root canal.</td>
<td>heating and cures on cooling after filled in a root canal.</td>
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<td></td>
</tr>
<tr>
<td>Dental root canal obturating point A metal or polymer point/cone suitable</td>
<td>Dental root canal obturating point A metal or polymer point/cone suitable</td>
<td>34791000</td>
<td>II</td>
<td>8-1</td>
<td>applicable</td>
</tr>
<tr>
<td>for filling of root canals. It is not intended for abutment of prostheses or</td>
<td>for filling of root canals. It is not intended for abutment of prostheses or</td>
<td></td>
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<tr>
<td>repair of crowns.</td>
<td>repair of crowns.</td>
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</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Hierarchy</td>
<td>Category</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Dental root canal filling material</td>
<td>A solid material used for filling of root canals.</td>
<td>70873000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental root canal sealing material</td>
<td>A material that cures without water and is intended for permanent sealing of the root canal, regardless of whether an obturating point is concurrently used. Materials intended for biological effects or containing drugs or biological raw materials are excluded. It is</td>
<td>36095000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Root canal filling solvent</td>
<td>A material used to soften filling materials such as gutta-percha.</td>
<td>70875000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental emergency kit</td>
<td>A kit of devices and materials to be used when an unexpected accident occurs in dental treatment. It contains the products needed by a general user to make a temporary restoration in an emergency without support from a dentist. Reinstallation and recovery of appearance and functions of a fallen crown, bridge, filling material and inlays can be</td>
<td>44406000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cavity varnish</td>
<td>A solution of single or multiple resin components dissolved in an organic solvent, used for protection of the dental pulp and sealing of the periphery during filling with amalgam restorations</td>
<td>35698000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental multipurpose glass polyalkenoate cement</td>
<td>A type of cement that cures by a reaction between aluminosilicate glass powder and alklenoic acid aqueous solution or between a mixture of aluminosilicate glass polyacid powder and water or organic acid aqueous solution. Cements containing pharmaceutical</td>
<td>70878000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental resin-modified glass polyalkenoate cement for temporary restoration</td>
<td>A material that composed of a resin component and glass polyalkenoate cement for dental filling, and intended for temporary restoration. Ones containing drugs are excluded.</td>
<td>70880000</td>
<td>II</td>
<td>8-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental alginate impression material</td>
<td>An impression material containing alginate as the primary component for gelation.</td>
<td>35863000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental polyether impression material</td>
<td>An elastic material primarily made of polyether, which forms a rubber-like material suitable for taking impressions after reaction.</td>
<td>35864000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental polysulfide impression material</td>
<td>An elastic material primarily made of polysulfide, which forms a rubber-like material suitable for taking impressions after reaction.</td>
<td>35865000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental silicone impression material</td>
<td>An elastic material primarily made of polysiloxane, which forms a rubber-like material suitable for taking impression after reaction.</td>
<td>35866000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental agar impression material</td>
<td>An impression material containing reversible agar hydrocolloid as a component for gelation.</td>
<td>35862000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental impression compound</td>
<td>A thermoplastic impression material used to take an impression of the oral cavity. It is a mixture of natural resin, filler, and lubricant.</td>
<td>34799000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental zinc oxide eugenol-based impression material</td>
<td>An impression material primarily made of zinc oxide and eugenol.</td>
<td>70885000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental impression material kit</td>
<td>A kit that combines a dental impression material, setting time regulator, mixing instrument, etc.</td>
<td>70886000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental optical impression auxiliary material</td>
<td>A material used to prevent diffuse reflection, etc. during optical impression-taking using a chairside dental CAD/CAM unit.</td>
<td>70888000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental resin-based impression material</td>
<td>A resin-based material used to take an impression of the oral cavity. (Dental polyether impression material, dental polysulfide impression material, and dental silicone impression material are excluded.)</td>
<td>70889000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Special Mark</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Denture adhesive</td>
<td>Powder-like or paste-like materials used for stabilizing a denture (removable denture) in the oral cavity. Materials defined by other names are excluded.</td>
<td>16388009</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Glue type denture adhesives</td>
<td>Powder, paste, or sheet-like material used to maintain adhesion of a removable denture to the oral mucosa.</td>
<td>16388010</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Liner type denture adhesives</td>
<td>An insoluble paste used to maintain sticking (by negative pressure) of a removable denture to the oral mucosa.</td>
<td>16388020</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental retention pin</td>
<td>An appliance implanted permanently in a tooth to retain or stabilize a dental restoration.</td>
<td>35868000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental precision ball attachment</td>
<td>An attachment composed of a bulbar (male) component and a ringed (female) component.</td>
<td>38576000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental precision bur attachment</td>
<td>A device comprising a ready-made metal bur, hook, sleeve, screw, etc. and used to secure a removable prosthetic appliance to a bar shaped appliance.</td>
<td>38577000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental precision magnetic attachment</td>
<td>A device that holds a removable prosthetic appliance by magnetic attraction.</td>
<td>38578000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental precision slide attachment</td>
<td>A device which is designed to fit the male component along the precision groove of the female component.</td>
<td>38580000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental precision elastic attachment</td>
<td>An attachment designed to allow enough play that can accommodate tooth-borne or mucosa-borne denture displacement caused by deformation of the basal seat mucosa so that excessive force is not exerted on the base.</td>
<td>38603000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Prefabricated root canal post</td>
<td>A ready made post or rod inserted into the prepared root canal for retention or reinforcement. The post may come in various shapes and sizes and may be made of an alloy, ceramic, fiber-reinforced plastic, etc.</td>
<td>38609000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental general-purpose acrylic resin</td>
<td>An acrylic resin used for a multi-purposes such as fabrication of temporary inlays, crowns, and bridges or repair of denture bases. It includes adjusting materials of curing time, etc.</td>
<td>70916010</td>
<td>8-①,7,5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>General-purpose dental acrylic resin kit</td>
<td>A kit containing dental, general-purpose acrylic resins and related appliances.</td>
<td>70916020</td>
<td>8-①,7,5-⑤</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental laboratory metal surface treatment material</td>
<td>A dental laboratory surface treatment agent used to make a surface of cast metal frames adherent or to reinforce its adhesiveness.</td>
<td>70917010</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental laboratory colour improvement metal surface treatment material</td>
<td>A dental laboratory surface treatment agent used to improve the color of surface of cast metal frames. It is not used for surface treatment by plating.</td>
<td>70917020</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental color masking material</td>
<td>A resin-based material used to mask the color of teeth, crown restorations, and metal bases. (Materials identified elsewhere as in &quot;Tooth surface coating material&quot; and &quot; Dental)</td>
<td>70919000</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Dental adhesive kit</td>
<td>A kit containing appliances used for routine adhesion operations in dental treatment. Those defined with other names and those that have pharmaceutical ingredients are excluded.</td>
<td>70920012</td>
<td>8-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Tariff Code</td>
<td>HS Code</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Dental laboratory adhesive material</td>
<td>A resin-based material for bonding/repair, used in fabrication of crown restorations and dentures and implanted in the oral cavity. It does not contain drugs. (Materials identified elsewhere as in “dental ceramic adhesive” and “dental metal adhesive” are excluded.)</td>
<td>70920022</td>
<td>II</td>
<td>8-1</td>
<td>—</td>
</tr>
<tr>
<td>Dental metal adhesive material</td>
<td>A material used to bond metal to a resin-based dental material.</td>
<td>70921000</td>
<td>II</td>
<td>8-1</td>
<td>—</td>
</tr>
<tr>
<td>Dental metal adhesive kit</td>
<td>A kit that contains dental metal adhesive materials and related tools.</td>
<td>70922000</td>
<td>II</td>
<td>8-1</td>
<td>—</td>
</tr>
<tr>
<td>Prefabricated root canal post kit</td>
<td>A kit comprising a ready-made post/rod, drill, wrench, gauge, etc. The post or rod is inserted into the prepared root canal for reinforcement. The drill, wrench, gauge, etc. are used for pretreatment before insertion of the post/rod.</td>
<td>70924000</td>
<td>II</td>
<td>8-1</td>
<td>—</td>
</tr>
<tr>
<td>Dental hypersensitive dentine desensitizer</td>
<td>A material applied to the tooth surface to reduce hyperesthesia of dentin (including prepared dentin). Materials with absorptivity or biological effects, or containing drugs or biological raw materials are excluded.</td>
<td>70926000</td>
<td>II</td>
<td>8-1</td>
<td>—</td>
</tr>
<tr>
<td>Long-term use occlusal splint dental material</td>
<td>A material used to fabricate dental occlusal splints that can be used for over 30 days.</td>
<td>70929000</td>
<td>II</td>
<td>5-5</td>
<td>—</td>
</tr>
<tr>
<td>Long-term use occlusal splint</td>
<td>A rigid or flexible appliance that covers the occlusal surface. It is used for over 30 days for retention of a displaced or loose tooth, treatment of clenching (habitual contraction of the jaw muscles), bruxism and their sequelae, and for temporary analgesia of pain in the muscle or temporomandibular joint (for example, temporomandibular joint disorder)</td>
<td>70930000</td>
<td>II</td>
<td>5-5</td>
<td>—</td>
</tr>
<tr>
<td>Long-term use dental molded polymer clasp</td>
<td>A ready-made dental clasp made of polymeric material that can be used for over 30 days.</td>
<td>70931000</td>
<td>II</td>
<td>5-5</td>
<td>—</td>
</tr>
<tr>
<td>Long-term use dental preformed metal clasp</td>
<td>A ready-made elastic metal clasp for removable partial dentures. This clasp can be used for over 30 days.</td>
<td>70932000</td>
<td>II</td>
<td>5-5</td>
<td>—</td>
</tr>
<tr>
<td>Dental lubricating material</td>
<td>Materials that provide lubricity by application to the surface of the denture base, artificial tooth or oral mucosa for the purpose of controlling discomfort caused by lack of lubrication between the denture and the oral mucosa. Those containing drugs and biological products are excluded.</td>
<td>70933000</td>
<td>II</td>
<td>5-5</td>
<td>—</td>
</tr>
<tr>
<td>Powered keratome</td>
<td>An electric device for making lamellar incisions in the cornea in ophthalmic surgery.</td>
<td>12222002</td>
<td>II</td>
<td>6</td>
<td>—</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Number</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Powered keratome blade</td>
<td>A spare blade for powered keratome. This is for single-use.</td>
<td>35137000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Water jet keratome</td>
<td>An ophthalmic surgery device used for shaving off the corneal tissue utilizing high-pressure water in nonpenetrating keratoplasty.</td>
<td>44249000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Bone cutter</td>
<td>A surgical device for penetrating the bone or separating one bone into two parts with a sharp blade(s). It usually consists of a manual or non-electrical device with one or more sharp blades. It may have two blades rotating around a central shaft and two short handles like forceps or cutting pliers. It is mainly used in orthopedic surgery and oral surgery.</td>
<td>10455000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use sclerotome</td>
<td>An ophthalmic surgical instrument used in sclerotomy. The device is for single-use.</td>
<td>13507002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use manual corneal trephine</td>
<td>A manual cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft. The device is intended for single-use.</td>
<td>14148012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use ophthalmic knife</td>
<td>A severing instrument with a handle and a blade of various shapes and sizes, used in surgery of the eye and surrounding area. The device includes a spare blade that is used after attachment to the reusable handle. The device is intended for single-use.</td>
<td>32764002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use scalpel</td>
<td>An instrument used to sever and separate body tissues during surgery. The device is a surgical instrument that usually has a handle and a blade of various shapes and sizes. Instruments categorized as a knife may be designed for other technological approaches. The device may be designed for sever specimens or objects other than body tissues. The device is intended for single-use.</td>
<td>35130002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use surgical saw</td>
<td>A manually operated or powered (by air, nitrogen, battery, AC power, etc.) device, which may be used alone or with a variety of attachments such as a vibrating blade or reciprocating blade. The device is usually designed for use in a specific field. The device may be used microscopically or macroscopically. The device can be used in many surgical procedures.</td>
<td>13448012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Powered surgical saw</td>
<td>13448022</td>
<td>II 9</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use saw</td>
<td>34821002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use file</td>
<td>11701002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use ophthalmic snare</td>
<td>32755002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use cranial bur</td>
<td>10520002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Airway needle</td>
<td>12732002</td>
<td>II 6</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use perforator</td>
<td>12989002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use nucleus pulposus resection device</td>
<td>70934000</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Powered corneal bur</td>
<td>32812000</td>
<td>II 6,9</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use dermatome blade</td>
<td>35134000</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use blood vessel surgical stripper</td>
<td>35377002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use ophthalmic forceps</td>
<td>16209002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use forceps</td>
<td>35079002</td>
<td>II 6</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Score</td>
<td>Applicable</td>
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<tr>
<td>Single-use surgical clamp</td>
<td>A surgical instrument used to hold, join, compress, or support an organ, tissue, or blood vessel in a nontraumatic manner. The device is intended for single-use.</td>
<td>10861002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use surgical probe</td>
<td>A thin, rod-shaped surgical instrument made of metal and soft materials. The device is used to explore sinuses, fistulae, and other cavities and wounds. The probe tip is designed for insertion into specific anatomical structures (e.g., for exploration of the mastoid process) and may be bent at right angles where it joins the shaft. The device is intended for single-use.</td>
<td>32870002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use eye speculum</td>
<td>A device to keep the eyelids open in ophthalmic surgery or examination. For example, the device is a surgical instrument with two arms connected at a pivot. It may come in various sizes, shapes, and contours. The distal end may be round and is used to dilate or stretch the tissue around the eye sockets when the instrument is used. The device is used during examination or eye surgery. The device is usually made of stainless steel and equipped with an automatic eyelid-opening/retaining mechanism. The device is intended for single-use.</td>
<td>35349002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use intraocular lens inserter</td>
<td>An instrument inserted into the eye to guide insertion/placement of an intraocular lens in surgery. The device is removed after insertion of the lens. The device is intended for single-use.</td>
<td>36061002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use tongue scraper</td>
<td>A wooden or metal instrument used to collect scrapings from the top of the tongue for diagnosis. The device is intended for single-use.</td>
<td>16308000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use ophthalmic curette</td>
<td>An ophthalmic abrasive instrument with a tip that is fenestrated, spoon-shaped, or ring-shaped, etc. The tip may be either pointed or round. The device is used to collect or resect ocular tissues. The device is for single-use.</td>
<td>32772002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use lens surgical spoon</td>
<td>A manually operated instrument used in treatment, resection, etc. of the lens in ophthalmic surgery. The device is for single-use.</td>
<td>35153002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use spoon</td>
<td>A instrument with handles and a spoon-shaped (dish-shaped) distal tip. The device is used in surgery, administration of drugs, or for some other purposes related to healthcare. The device is intended for single-use.</td>
<td>41716002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use ophthalmic hook</td>
<td>A surgical instrument that has a rod-shaped handle with a tapered distal tip. The shape of distal end varies: it may be curved or bent with a round or pointed tip. The device is intended for single-use.</td>
<td>35314002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use orbit retractor</td>
<td>An ophthalmic surgical instrument used to open up the incision on the eye or surrounding structures, or to fixate the eyeball. The device is intended for single-use.</td>
<td>13381002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Cardiac insulation pad</td>
<td>A thin, flexible pad that is placed around the heart for hypothermic cardioplegia in heart surgery using extracorporeal circulation. The device helps prevent a rapid return of the cardiac temperature. The device is intended for single-use.</td>
<td>35973000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use scleral plug</td>
<td>A nail-like plug inserted into the wound opening after removal of a chip, etc. in vitreous surgery. The device is intended for single-use.</td>
<td>70946000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use retractor</td>
<td>A surgical device used to separate tissues or anatomical structures. The device establishes access to an organ or tissue by exposing the target and enables examination or treatment. The device is intended for single-use. The device may have metal arms with a spatula.</td>
<td>13373002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Single-use organ fixation pelotte</td>
<td>A device used in therapy or examination to fixate or retain an organ to its original position. The device is intended for single-use.</td>
<td>70954000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use ophthalmic surgical spatula</td>
<td>A surgical instrument shaped like a spatula, etc., that is usually made of stainless steel, etc. and used for application of a substance to the eye, treatment of ocular tissue, or removal of substances from the eye or surrounding structures. The device may have a hollow shaft so that it fits into the guide pin placed in the precise location prior to when the device is attached to a surgical drilling and reaming machine and rotated at the recommended speed to cut through the bone and tissue. It is usually flexible and has a hollow shaft so that it fits into the guide pin placed in the precise location prior to when the device is attached to a surgical drilling and reaming machine and rotated at the recommended speed to cut through the bone and tissue.</td>
<td>32754002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgical cannulated drill</td>
<td>A device that establishes a passageway with the same diameter as that of the drill bit when the device is attached to a surgical drilling and reaming machine and rotated at the recommended speed to cut through the bone and tissue. It is usually flexible and has a hollow shaft so that it fits into the guide pin placed in the precise location prior to when the device is attached to a surgical drilling and reaming machine and rotated at the recommended speed to cut through the bone and tissue.</td>
<td>11332000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Biopsy drill</td>
<td>A drilling device (a drill bit) used for extracting (cutting off) a small piece of bone or cartilage for microscopy. Necessary operations can be performed when it is attached to a manual or electric surgical perforator and rotated at an appropriate speed.</td>
<td>11330000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered orthopaedic reamer</td>
<td>An electric orthopedic device used to open or enlarge a medullary cavity for insertion of other instruments in artificial joint replacement or fracture fixation.</td>
<td>35297002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Manually-operated orthopaedic injector</td>
<td>A manually operated syringe-like device used to inject orthopedic (bone) cement, artificial bone, etc. into the surgical site excluding the spine. Single-use components may be included.</td>
<td>70956000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use instrument for osteosynthesis</td>
<td>A manually operated instruments such as a manual bone drill, calcaneal retractor, and pelvic clamps used mainly in orthopedic osteosynthesis. Only manually operated devices are included. The device is intended for single-use.</td>
<td>70958002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered orthopaedic cement dispenser</td>
<td>An electric syringe-like device used to inject orthopedic (bone) cement into the surgical site. The device may be attached to an integrated power unit that pushes the plunger.</td>
<td>35809002</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Battery-powered surgical drill handpiece</td>
<td>A handpiece with a chuck used with drill bits, bone tap, or wire. The device runs on rechargeable batteries. A cannula may be inserted in the device so that it may be used over a guide wire. The device is designed for microscopic or macroscopic use.</td>
<td>37867010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrically-powered surgical drill</td>
<td>A handpiece with a chuck used with drill bits, bone tap, or wire. The device is electrically powered. The device may have a hollow center for use over a guide wire. The device is designed for microscopic or macroscopic use.</td>
<td>37867020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered surgical drill motor</td>
<td>A device that transmits rotation force from the surgical drilling motor to a surgical drill via a rotating cable (Bowden cable). Electricity is usually provided by the main power supply. The general type of this device group appears to reflect conventional technologies.</td>
<td>43915000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered bone operating instrument</td>
<td>An instrument used in bone surgery. This device is electrically powered.</td>
<td>70959010</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Battery-powered bone operating instrument</td>
<td>A surgical device used in bone surgery such as osteosynthesis. The device runs on rechargeable batteries.</td>
<td>70959020</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>IEC 60601-1 Mark</td>
<td>CE Mark</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Single-use intramedullary canal cleaning brush</td>
<td>A surgical instrument used to remove blood clots and bone fragments from the medullary canal before injection of orthopedic cement. The device commonly has a handle on one side and stinging hair, fiber, or thorns on the other. The stinging hair, fiber, or thorns may be planted on a plane or radially from the instrument axis. The handle and stinging hair may be either soft or rigid. The device is intended for single-use.</td>
<td>35589002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use orthopaedic file</td>
<td>A long tapered surgical cutting tool with teeth that is used to cut and enlarge a hole in bone tissue. The device is sterilized and intended for single-use.</td>
<td>36167002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use manually-operated surgical drill handpiece</td>
<td>A manually operated handpiece with a chuck, used with drill bits, bone tap, or wire, etc. The device is also called a retainer and bit. A cannula may be inserted in the device so that it may be used over a guide wire. The device is intended for single-use.</td>
<td>36235002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use orthopaedic bur</td>
<td>A small rotary shaft made of hard metal such as steel with grooves of various shapes or a cutting plane on one end, used to cut or shape a hole in bone in maxillofacial surgery, spinal surgery, or other major or minor bone surgery. The device is intended for single-use.</td>
<td>36249002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use surgical drill attachment</td>
<td>An appliance connected to a manually operated or powered handpiece to perform specific task, drilling, and reaming, and to introduce or guide a wire, etc. The device comes with a reduction gear that enables fine speed control for specific tasks. A cannula may be placed in the device so that it may be used over a guide wire. The device is intended for single-use.</td>
<td>37870002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use surgical crown drill bit</td>
<td>A hollow boring tool used as a crown drill or hollow mill. The device is used to remove the shaft of a broken screw without head, or to collect the central portion of the bone in biopsy. The device is intended for single-use.</td>
<td>37871002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use bone operating instrument</td>
<td>A surgical device used in bone surgery such as osteosynthesis. The device is manually operated. The device is intended for single-use.</td>
<td>70962012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use instrument for spinal surgery</td>
<td>An instrument used for spinal surgery such as spinal fusion. The device is manually operated. The device is intended for single-use.</td>
<td>70963012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Battery-powered spinal cord operating instrument</td>
<td>An instrument used in spinal surgery such as spinal fusion. The device runs on rechargeable batteries.</td>
<td>70963022</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use instrument for joint surgery</td>
<td>An instrument used in joint surgery such as artificial joint replacement. The device is manually operated. The device is intended for single-use.</td>
<td>70964012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Battery-powered joint operating instrument</td>
<td>An instrument used in joint surgery such as artificial joint replacement. The device runs on rechargeable batteries.</td>
<td>70964022</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered dental implant surgical device</td>
<td>A device used while connected to an active equipment in dental implant surgery. The device may be designed for single-use only.</td>
<td>70965002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use instrument for ligament/tendon surgery</td>
<td>A device used in surgery on tendons/ligaments such as ligament reconstruction. The device is manually operated. The device may come with a suture needle. The device is intended for single-use.</td>
<td>70966002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Level</td>
<td>Level</td>
<td>Applicable</td>
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<tr>
<td>Power tool torque control unit</td>
<td>A device that is connected with an electrical device or electrical device system and used for adjusting the torque of the electrical device. It provides power to perform the treatment by weakening or strengthening the torque of the electrical device, such as by inserting or by fastening an orthopedic fixation screw or a denture fixation screw.</td>
<td>43894000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthopaedic prosthesis implantation instrument</td>
<td>A tool specifically designed to be used for insertion of an orthopedic artificial implant or a prosthesis. It may work as a standard interface between the parts of the prosthesis when it is inserted, or it may be used for confirming appropriate spatial localization, fixing the location for a device (a sensor) holding parts during cement fixation, or making a check for cement quality.</td>
<td>13180000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered orthopaedic cement extractor</td>
<td>A set of electric surgical instruments usually used in artificial joint replacement to remove orthopedic (bone) cement, which was used to implant an artificial joint. The set may include a slam hammer, chisel, comparable electric devices to crack and remove bone.</td>
<td>44598000</td>
<td>II</td>
<td>9,12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dilator for catheter</td>
<td>A device used to dilate or enlarge a lumen or opening for catheter insertion. (usually used in surgery)</td>
<td>32338000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use medical dilator</td>
<td>A non-electrical dilating instrument. The device is intended for single-use. Electrical devices are excluded.</td>
<td>70969002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Lens for ophthalmic surgical laser</td>
<td>A lens used with an ophthalmic surgical laser. It is usually transparent and guides the laser beam to the eye, eye socket, or surrounding skin for coagulation/cutting.</td>
<td>40238000</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable diagnostic contact lens</td>
<td>A contact lens worn by a patient to help diagnosis of specific eye disorders/conditions. The device is reusable.</td>
<td>34651010</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use diagnostic contact lens</td>
<td>A contact lens worn by a patient to help diagnosis of specific eye disorders/conditions. The device is intended for single-use.</td>
<td>34651020</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Electroretinograph corneal electrode</td>
<td>An electrode used in contact with the corneal surface or the mucosa near the cornea for transmission of potential signals in electroretinography. It may contain a conductor for measurement of the reference potential of the cornea in addition to that for corneal potential.</td>
<td>70972000</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Gonioscope</td>
<td>A device used in gonioscopy.</td>
<td>11894000</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Intraocular pressure reducer</td>
<td>A manually operated ophthalmic surgical device for reducing intraocular pressure in ophthalmic surgery.</td>
<td>15048000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Aesthesiometer</td>
<td>An apparatus used to measure the corneal perceptual sensitivity by applying a nylon filament to the cornea.</td>
<td>70974000</td>
<td>II</td>
<td>5-①&quot;</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable contraceptive pessary</td>
<td>A circular device made of silicone or plastic material, etc. that is placed in the vagina and used to mechanically prevent conception. This may be a reusable device.</td>
<td>35237000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive cervical cap</td>
<td>A device that is inserted into the cervix and works as a physical barrier to prevent spermatic invasion into the uterus. It consists of a cup with a round edge made of elastic rubber. A medical professional adjusts the size to make it fit the perimeter of the cervix.</td>
<td>32608000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive sponge</td>
<td>A bubble-like device that works as a physical barrier to prevent spermatic invasion into the uterus when it is inserted into the vagina. This device absorbs semen. The one containing spermicides destroys sperm</td>
<td>35931000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Latex surgical glove</td>
<td>A natural rubber garment, designed to protect the patient and wearer from cross infection when used in medical or dental surgery.</td>
<td>40548000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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</tr>
<tr>
<td>Non-latex surgical glove</td>
<td>A garment made of synthetic material and designed to protect the patient and wearer from cross infection when used in medical or dental surgery.</td>
<td>40549000</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Delivery procedure set</td>
<td>A set of materials and tools such as gauze and catheter used for disinfection, hemostasis, draining, etc. of the mother and neonate during parturition.</td>
<td>70978000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electric massager</td>
<td>An electrically powered massager designed especially for home use. For instance, its head or other specifically shaped component vibrates and is applied to the desired body part for massage. The vibrating head can be changed to another of a different size or shape. Other variants are used to compress or massage a body part using pneumatic pressure. The device is also used to stimulate or massage muscles.</td>
<td>34662000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use pneumatically-powered massager</td>
<td>A massager designed especially for home use and operates only with pneumatic pressure.</td>
<td>34663000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use suction massager</td>
<td>A massager designed to induce tactile sensation especially for home use. The user can operate it on his/her own for therapeutic stimulation and massage of muscles. The device includes suction cups or variants. The device is not suitable for hospital or clinic use.</td>
<td>34664000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric massager with needles and a protection pipe</td>
<td>A device used by applying a vibrating pipe tip and needle points perpendicularly to the skin. The device contains multiple needles inside the protective pipe.</td>
<td>70979000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use heating digital compressor</td>
<td>Home use therapy equipment with round protrusions heated electrically, etc., imitating acupressure therapy with its own weight or under compression.</td>
<td>70980000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use digital compressor with rollers</td>
<td>Home use therapy equipment with protruding rollers imitating acupressure therapy with its own weight or under compression.</td>
<td>70981000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use pneumatic digital compressor</td>
<td>Pneumatic equipment imitating acupressure therapy which is designed especially for home use. For example, rounded protrusions pneumatically press the user's body and imitates acupressure therapy. The protrusions can be changed to another of different size.</td>
<td>70982000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use ultrasonic bubble bath</td>
<td>An apparatus that generates bubbles by blowing pressurized warm water with air into the bath, producing ultrasonic waves from the bubbles. It does not use electrical oscillation to generate ultrasonic waves.</td>
<td>70983000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use air bubble bath</td>
<td>Home use equipment that blows bubbles into warm water by mechanisms such as passing air through a porous board.</td>
<td>70984000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use whirlpool bath</td>
<td>Home use equipment that blows warm water inside a bathtub so that the water flow rotates in the bathtub and forms a vortex.</td>
<td>70985000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use hydro-massage therapy bath</td>
<td>A bathtub equipped with a nozzle that generates a large quantity of jetted water to thereby provide treatment massaging effects. This device can be used for a patient with rheumatism in pain relief therapy which is also known as non-invasive water therapy.</td>
<td>34667000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use low-frequency therapy equipment</td>
<td>Home use equipment that applies a mild, low-frequency electric current to the skin surface for treatment.</td>
<td>70986000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electric potential therapy apparatus</td>
<td>Home use equipment that puts the body on an alternating electric field or direct electric field, or applies an electric potential to the body in an insulated state, for treatment.</td>
<td>70987000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use shortwave diathermy unit</td>
<td>Home use treatment equipment that radiates high-frequency (from 13 to 27.12 MHz) electromagnetic energy to a specific site of the body. It is operated for the purpose of providing deep tissue heating for the tissues inside the body for mitigation of selected 74668000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Home use short wave therapy unit</td>
<td>Home use equipment that irradiates a desired body surface with electromagnetic energy in the high-frequency band (from 13 MHz to 2450 MHz) to heat the tissue deep inside the irradiated area for treatment</td>
<td>70988000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use high frequency therapy equipment</td>
<td>Home use equipment that irradiates a desired body surface with electromagnetic energy in high-frequency band (about 9 MHz) to achieve vasodilation or improve blood flow.</td>
<td>70989000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use combination electric therapy apparatus</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and an electric potential therapy apparatus, or an electric massager and an electric potential therapy apparatus etc.</td>
<td>70990000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential/heat/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus, heat therapy equipment, and an electric massager.</td>
<td>70991000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/electric potential/ultrashort wave combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment, an electric potential therapy apparatus, and an ultra-short wave therapy unit.</td>
<td>70992000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/electric potential/heat combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment, an electric potential therapy apparatus, and heat therapy equipment.</td>
<td>70993000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/heat/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment, heat therapy equipment, and an electric massager.</td>
<td>70994000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/electric potential combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and an electric potential therapy apparatus.</td>
<td>70995000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/ultrashort wave combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and an ultra-short wave therapy unit.</td>
<td>70996000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and an electric massager.</td>
<td>70997000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/heat combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and heat therapy equipment.</td>
<td>70998000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Low-frequency/moxibustion combined home use medical device</td>
<td>Home use therapeutic equipment combining low-frequency therapy equipment and a moxibustion apparatus.</td>
<td>70999000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential/ultrashort wave combined home use medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus and an ultra-short wave therapy unit.</td>
<td>71000000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential/heat combined home use medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus and heat therapy equipment.</td>
<td>71001000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electric potential/moxibustion combined medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus and a moxibustion apparatus.</td>
<td>71002000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus and an electric massager.</td>
<td>71003000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric potential/air massage combined home use medical device</td>
<td>Home use therapeutic equipment combining an electric potential therapy apparatus and a pneumatically-powered massager.</td>
<td>71004000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Heat/moxibustion combined home use medical device</td>
<td>Home use therapeutic equipment combining a heat therapy equipment and a moxibustion apparatus.</td>
<td>71005000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Heat/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining a heat therapy equipment and an electric massager.</td>
<td>71006000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Moxibustion/electromassage combined home use medical device</td>
<td>Home use therapeutic equipment combining a moxibustion apparatus and an electric massager.</td>
<td>71007000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric sleep inducer</td>
<td>An apparatus that induces sleep by application of a weak electric pulse patterned for a sympatheoinhibitory effect to the head.</td>
<td>71010000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electric needle</td>
<td>A home use electrical needle that generates voltage from the piezoelectric element to provide electrical stimulation to an affected site of the body.</td>
<td>71011000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use infrared light therapy unit</td>
<td>A home use therapy device using for infrared radiation.</td>
<td>71012000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use ultraviolet light therapy unit</td>
<td>A home use therapy device for ultraviolet radiation.</td>
<td>71013000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use carbon arc light therapy unit</td>
<td>Home use phototherapy equipment to treat an affected site using a carbon arc generated by arc discharge with a carbon rod as the electrode.</td>
<td>71014000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electromagnetic induction therapy apparatus</td>
<td>Home use therapy equipment that generates a magnetic field with the use of alternating current and uses magnetism for treatment.</td>
<td>71015000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use magnetic induction therapy apparatus with permanent magnet</td>
<td>Home use therapy equipment that uses the magnetism of a permanent magnet for treatment.</td>
<td>71016000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use heat therapy equipment</td>
<td>Home use therapy equipment that applies thermal stimulation using electric heat for treatment (excluding moxibustion apparatus).</td>
<td>71017000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Moxibustion apparatus</td>
<td>A home use therapy apparatus that applies thermal stimulation to a target area for treatment.</td>
<td>71018000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use ultrasonic inhaler</td>
<td>A home use apparatus that atomizes a solution by ultrasonic vibration for inhalation.</td>
<td>71020000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use electrically-powered inhaler</td>
<td>A home use apparatus that atomizes a solution by compressed air for inhalation.</td>
<td>71021000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Detailed Description</td>
<td>HS Code</td>
<td>ST</td>
<td>Quantity</td>
<td>Applicable</td>
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</tr>
<tr>
<td>Home use electrically-heated inhaler</td>
<td>A home use apparatus that generates steam by electric heat and atomizes a solution using a steam blast for inhalation.</td>
<td>71022000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Batch process water electrolyzer</td>
<td>A home use apparatus that stores drinkable water containing calcium ions for a period and electrolyzes it to produce drinkable alkaline electrolyzed water and undrinkable acidic electrolyzed water.</td>
<td>71023000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Continuous flow water electrolyzer</td>
<td>A home use apparatus connected to a water outlet that electrolyzes drinkable water containing calcium ions to produce drinkable alkaline electrolyzed water and undrinkable acidic electrolyzed water.</td>
<td>71024000</td>
<td>II</td>
<td>11</td>
<td>applicable</td>
</tr>
<tr>
<td>Pocket-size hearing aid</td>
<td>A sound amplifier to assist hearing of patients with hearing loss. This device is composed of a part worn somewhere other than the head, and an ear mold, which is connected to the other part, inserted in the ear canal, and reproduces amplified sound.</td>
<td>30082000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Behind-the-ear hearing aid</td>
<td>A sound amplifier to assist hearing of patients with hearing loss. This device is composed of a part placed behind the ear lobe, and an ear mold, which is connected to the other part, inserted in the ear canal, and reproduces amplified sound.</td>
<td>34671000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Face-plate hearing aid</td>
<td>A hearing aid composed of an amplifier, controller, and battery holder. The device may have an integrated earphone and microphone or come with separate earphone and microphone. The device is attached to a case or shell, which is shaped according to the ear.</td>
<td>33953000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>In-the-ear hearing aid</td>
<td>A sound amplifier to assist hearing of patients with hearing loss. This device in its entirety fits within the ear canal and ear lobe. The amplified sound is reproduced in the ear canal.</td>
<td>34672000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Modular in-the-ear hearing aid</td>
<td>A hearing aid with a uniform external case not designed to fit individual user's ear.</td>
<td>41193000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Custom-made in-the-ear hearing aid</td>
<td>An in-the-ear hearing aid with a case or shell made to fit individual user's ear and with the internal circuit also adjusted to meet their needs.</td>
<td>41208000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Canal hearing aid</td>
<td>A small hearing aid that is worn almost completely in the ear canal. The device is a smaller version of the in-the-ear hearing aid.</td>
<td>41209000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Completely-in-the-canal hearing aid</td>
<td>A hearing aid that is smaller than canal hearing aids and placed very close to the tympanic membrane.</td>
<td>41211000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Spectacle hearing aid</td>
<td>A hearing aid with all of its components placed inside the temple (or temples) of spectacles. The sound is propagated from the spectacles by air conduction.</td>
<td>34673000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Programmable hearing aid</td>
<td>A device that aids persons with hearing impairment. Its properties are configured by software.</td>
<td>17666000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Tinnitus masker</td>
<td>A device that delivers noise to the wearer's ears to mask ear noise. The device is typically worn like a hearing aid.</td>
<td>30899000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
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<td>Category</td>
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</tr>
<tr>
<td>Bone-conduction hearing aid</td>
<td>A hearing aid worn on the head that is attached to spectacles or headband and propagates the sound through the bone conduction receiver.</td>
<td>33993000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Digital hearing aid</td>
<td>A device that is designed to aid persons with hearing impairment by digitalization of sound signals, which are processed in a digital circuit using a digital-processing algorithm.</td>
<td>41207000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Headband hearing aid</td>
<td>A hearing aid that is mostly housed in a case attached to a headband. The amplified sound is propagated to the ear via an earphone or sound tube.</td>
<td>41212000</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Wound pad for home use</td>
<td>A pad made by materials such as hydrocolloid, which is used to protect wounds at home. It is used to protect wounds such as mild cut, abrasion, puncture, scratch, and shoe sore, as well as mild burn. It maintains a moist environment to promote pain relief and healing.</td>
<td>71025000</td>
<td>II</td>
<td>4-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Home use acupuncture unit</td>
<td>An acupuncture device designed to be used by a user who performs acupuncture at home.</td>
<td>34675002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Vaginal douche</td>
<td>An apparatus designed to deliver a liquid (usually solution) directly into the vaginal cavity as a douche. The device is composed of a bag or bottle with an attached tube or nozzle for manual use. The device may be designed for a single-use with a prefilled cleaning solution.</td>
<td>32616000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive micro-condom</td>
<td>A small sheath made of latex or a synthetic material to cover the glans penis for the purpose of contraception.</td>
<td>34030000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive, condom, female</td>
<td>A sheath type device with rings at both ends that is inserted into the vagina and kept during coitus to prevent sperm invasion into female reproductive tract or prevent transmission among sex partners of microorganisms causing sexually transmitted diseases.</td>
<td>36281000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Contraceptive, condom, male</td>
<td>A sheath type device that cover the penis during coitus to prevent sperm invasion into female reproductive tract or prevent transmission among sex partners of microorganisms causing sexually transmitted diseases.</td>
<td>36282000</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Capsule imaging and tracking device</td>
<td>A capsule-shaped medical device used for observation and diagnosis of the gastrointestinal tract. It contains a radio transmitter that records image data while moving inside the gastrointestinal tract peristaltically and sends the data wirelessly and non-invasively to the receiver outside the body while moving inside the body or after.</td>
<td>71027000</td>
<td>II</td>
<td>10-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use vertebral orthotic</td>
<td>A device used for the balloon kyphoplasty which is intended to restore the vertebral height at a bone fracture site and to form a cavity inside the trabecular bone for orthopedic bone cement injection. An expandable balloon is attached to the distal end of the device.</td>
<td>47021002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
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<tr>
<td>Dental air-powered drill handpiece</td>
<td>A pneumatically driven handpiece with a chuck to connect a dental device, such as dental burs and reamers, which rotates, vibrates, repeats rotation, reciprocates, or moves in combination of these motions. The device has an integrated pneumatic motor.</td>
<td>40958032</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Ion penetration percutaneous local anaesthesia apparatus</td>
<td>A device for percutaneously promoting penetration of an anesthetic solution by passing a weak electric current through the human body in ionized local anesthesia.</td>
<td>70575022</td>
<td>II</td>
<td>6,9</td>
<td>applicable</td>
</tr>
<tr>
<td>Blood component separation apparatus</td>
<td>A device used for separation of specific blood components with a blood component separation kit.</td>
<td>58329002</td>
<td>II</td>
<td>3-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Patient-adaptive, single-use device for joint surgery</td>
<td>A surgical device used for joint surgery including arthroplasty with prosthetic joint replacement. It is a manual machine designed and manufactured to fit an individual patient. Only manually operated types are included. This device is for single-use.</td>
<td>70964212</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Balloon-guided small-intestine endoscopy system</td>
<td>A system consisting of an endoscope, an over-tube with a balloon, a balloon and a balloon controller installed on an endoscope, etc. It is inserted into the upper or lower gastrointestinal tract orally or via the anus, and fixes the endoscope and over-tube in the intestinal tract by inflating the balloon. The endoscope and over-tube fixed in the</td>
<td>71033002</td>
<td>II</td>
<td>5-②,5-⑥</td>
<td>applicable</td>
</tr>
<tr>
<td>Workstation for cardiac mapping system</td>
<td>An operational unit that percutaneously navigates (advances in the right direction and to the right location) devices including a catheter applies to the heart, to the targe of the heart by using dedicated software. This unit operates the catheter in combination with a device that supplies magnetic force or mechanical power, etc.</td>
<td>31742002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use infusion/drainage blunt needle</td>
<td>A device that has a long, thin, hollow tube for administration of solutions including drugs to a patient or for draining solutions from the body. This device has a blunt tip to prevent damage to the insertion site. This device is for single-use.</td>
<td>30889012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Electronic urine glucose meter</td>
<td>A urine glucose meter specifically dedicated for healthcare. It is a dedicated automatic or semi-automatic healthcare device with a sensor for measurement of the urine glucose level in daily life.</td>
<td>70188012</td>
<td>II</td>
<td>–</td>
<td>applicable</td>
</tr>
<tr>
<td>Urine chemistry for self monitoring</td>
<td>An automatic or semi-automatic device dedicated to self monitoring to identify and measure chemical substances in the urine with a test strip or a sensor.</td>
<td>70186000</td>
<td>II</td>
<td>–</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Specific Information</td>
<td>Approval Status</td>
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</tr>
<tr>
<td>Urine glucose meter for self monitoring</td>
<td>An automatic or semi-automatic device dedicated to self monitoring to identify and measure urine glucose with a test strip or a sensor.</td>
<td>70188000</td>
<td>II</td>
<td>—</td>
<td>applicable</td>
</tr>
<tr>
<td>Magnetic stimulator for urinary incontinence treatment</td>
<td>A non-implantable magnetic stimulator used for treatment of urinary incontinence. It usually consists of a main body equipped with a power supply part and a stimulation unit that provides magnetic energy.</td>
<td>71035002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Patient-adaptive, single-use device for bone surgery</td>
<td>A surgical device used for bone surgery including osteosynthesis surgery. It is designed and manufactured to fit each individual patient. It should be a manually operated device. This device is for single-use.</td>
<td>70962212</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>MRI-combined positron CT system</td>
<td>An integrated system combining systems for positron emission tomography computed tomography and magnetic resonance imaging. This system is both a three-dimensional (tomographic) imaging system that generates images of the distribution of positron released from positron-emitting radiopharmaceuticals administered orally or intravenously, and a magnetic resonance imaging system capable of generating two-dimensional or three-dimensional magnetic resonance images. Either system can be used independently. The system uses a variety of digital technologies for scanning and reconstruction, including the use of combination of the fast and slow digital imaging processing.</td>
<td>58250002</td>
<td>II</td>
<td>10⁻¹,10⁻²</td>
<td>applicable</td>
</tr>
<tr>
<td>Thermoregulation system</td>
<td>A system for temporary use that adjusts body temperature by heat exchange with the human body via a cuff placed in the pharynx or esophagus of a patient who needs temperature control. It consists of the cuff, where the perfusate circulates, and the control unit, where perfusate temperature is controlled, circulation and body temperature are monitored, and an alarm is given when necessary.</td>
<td>71036002</td>
<td>II</td>
<td>5⁻⁶,9</td>
<td>applicable</td>
</tr>
<tr>
<td>Decontamination disinfector for ultrasound probe</td>
<td>A disinfector that removes wastes or stains from, and disinfects the lumen and surface of an ultrasonic probe.</td>
<td>45058002</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
</tr>
<tr>
<td>Digital impression taking apparatus</td>
<td>A device used for collecting three-dimensional shape data with digital methods to be provided for computer-aided design (CAD) and computer-aided manufacturing (CAM) of dental restorations, etc.</td>
<td>38597012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Transcutaneous catheter with intravascular valve cutter</td>
<td>A flexible tube with a blade used in revascularization by bypass grafting. A peripheral vein is diverted to an artery in bypass grafting. This tube is inserted percutaneously into the vein, with the vein left under the skin without being removed or collected, and incises the venous valve without causing damage, and loses its function.</td>
<td>14339002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Specification</td>
<td>Grade</td>
<td>Apply</td>
<td>Applicable</td>
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<tr>
<td>Valve function assessment balloon catheter for valvuloplasty</td>
<td>A flexible tube used for postoperative assessment of valve regurgitation before restart of the heartbeat in valvuloplasty with synthetic Vascular prosthesis replacement in the root of the ascending aorta.</td>
<td>71038002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for using with general-purpose X-ray diagnostic system</td>
<td>A software, which is designed to process data obtained from the following devices: mobile analogue general-purpose diagnostic X-ray system, portable analogue general-purpose diagnostic X-ray system, stationary analogue general-purpose diagnostic X-ray system, mobile digital general-purpose diagnostic X-ray system, and portable digital general-purpose diagnostic X-ray system.</td>
<td>37626032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for general-purpose integral diagnostic X-ray system</td>
<td>A software for medical device, which is intended to process data obtained from the following devices: mobile analogue general-purpose integral diagnostic X-ray system, portable analogue general-purpose integral diagnostic X-ray system, stationary analogue general-purpose integral diagnostic X-ray system, mobile digital general-purpose integral diagnostic X-ray system, and portable digital general-purpose integral diagnostic X-ray system. The</td>
<td>37626042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for using with mammography-combined diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a combined diagnostic mammography-radiography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70001012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for using with general-purpose fluoroscopic diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from the following devices: stationary analogue general-purpose fluoroscopic diagnostic X-ray system, mobile analogue general-purpose fluoroscopic diagnostic X-ray system, portable analogue general-purpose fluoroscopic diagnostic X-ray system, mobile digital general-purpose fluoroscopic diagnostic X-ray system, and portable digital general-purpose fluoroscopic diagnostic X-ray system. The</td>
<td>37621032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for general-purpose integral fluoroscopic diagnostic X-ray system</td>
<td>A software which is designed to process data obtained from the following devices: stationary analogue general-purpose integral fluoroscopic diagnostic X-ray system, mobile analogue general-purpose integral fluoroscopic diagnostic X-ray system, mobile digital general-purpose integral fluoroscopic diagnostic X-ray system, mobile analogue general-purpose integral fluoroscopic diagnostic X-ray system, and mobile digital general-purpose integral fluoroscopic diagnostic X-ray system.</td>
<td>37621042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for using with cardiovascular fluoroscopic diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from the following devices: mobile digital angiographic fluoroscopic diagnostic X-ray system, stationary analogue angiographic fluoroscopic diagnostic X-ray system, and stationary digital angiographic fluoroscopic diagnostic X-ray system. The</td>
<td>37612012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for mammographic diagnostic X-ray system</td>
<td>A software which is designed to process data obtained from the following devices: stationary analogue mammographic diagnostic X-ray system, mobile analogue mammographic diagnostic X-ray system, and mobile digital mammographic diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37630012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for using with uro/gynaecological fluoroscopic diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from the following devices: mobile digital uro/gynaecological fluoroscopic diagnostic X-ray system, mobile analogue uro/gynaecological fluoroscopic diagnostic X-ray system, stationary digital uro/gynaecological fluoroscopic diagnostic X-ray system, and stationary analogue uro/gynaecological fluoroscopic diagnostic X-ray system. The</td>
<td>37615012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for public abdominal health screening diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from an abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37675032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for public thoracic health screening diagnostic X-ray system</td>
<td>A software which is designed to process data obtained from a thoracic public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37627052</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for public thoracic and abdominal health screening diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a thoracic and abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37627062</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for abdominal health screening integral diagnostic X-ray system</td>
<td>A software for medical device, which is designed to process data obtained from an abdominal public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37675042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for thoracic public health screening integral diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a thoracic public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37627072</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for integral thoracic and abdominal public health screening integral diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a thoracic and abdominal public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37627082</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for dental panoramic X-ray system</td>
<td>A software for medical device, which is designed to process data obtained from a dental public health screening panoramic X-ray system, an analogue dental panoramic X-ray system, or a digital dental panoramic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70002012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for dental panoramic/tomographic X-ray system</td>
<td>A software for medical device, which is designed to process data obtained from an analogue dental panoramic/tomographic X-ray system or a digital dental panoramic/tomographic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37668012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for general-purpose dental extraoral X-ray system</td>
<td>A software, which is designed to process data obtained from an analogue general-purpose dental extraoral X-ray system or a digital general-purpose dental extraoral X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37636012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for cephalometric diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a cephalometric diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37677032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for cephalometric integral diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from a cephalometric integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37677042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray computed tomography system</td>
<td>A software, which is designed to process data obtained from a limited view field X-ray computed tomography system or a whole body X-ray computed tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37619012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for arm type X-ray computed tomography system</td>
<td>A software, which is designed to process data obtained from an arm type X-ray computed tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70006012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nuclear medicine gamma camera</td>
<td>A software, which is designed to process data obtained from a stationary nuclear medicine gamma camera system or a mobile nuclear medicine gamma camera system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40640012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for SPECT system</td>
<td>A software, which is designed to process data obtained from a nuclear medicine rotating detector SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40642012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nuclear medicine positron emission tomography system</td>
<td>A software, which is designed to process data obtained from a nuclear medicine positron emission tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40644012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ultrasound imaging system</td>
<td>A software, which is designed to process data obtained from an ultrasound imaging system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36208012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for bone absorptiometer ultrasound system</td>
<td>A software, which is designed to process data obtained from a bone absorptiometer ultrasound system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40779012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for MRI system</td>
<td>A software, which is designed to process data obtained from the following devices: resistive magnet mammographic MRI system, resistive magnet whole body MRI system, resistive magnet head/extremity imaging MRI system, resistive magnet cardiovascular MRI system, superconducting magnet mammographic MRI system, superconducting MRI system.</td>
<td>37611012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for computed radiography</td>
<td>A software, which is designed to process data obtained from a computed radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70023012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray flat-panel detector-recorded digital radiography</td>
<td>A software, which is designed to process data obtained from an X-ray flat-panel detector-recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored used by the software.</td>
<td>70026012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for continuous measurement electronic thermometer</td>
<td>A software for medical device, which is designed to process data obtained from a continuous measurement electronic thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>14032032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for zero heat flow method thermometer</td>
<td>A software, which is designed to process data obtained from a zero heat flow method thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70043012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ear infrared thermometer</td>
<td>A software, which is designed to process data obtained from an ear infrared thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17887012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for automatic electronic sphygmomanometer</td>
<td>A software for medical device, which is designed to process data obtained from an automatic electronic sphygmomanometer or a manually-operated electronic sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16173022</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for medical electronic sphygmomanometer</td>
<td>A software, which is designed to process data obtained from a medical electronic sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16173032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ultrasonic fetal heart detector</td>
<td>A software, which is designed to process data obtained from an ultrasonic fetal heart detector. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35068012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for general-purpose electrocardiograph</td>
<td>A software, which is designed to process data obtained from a general-purpose electrocardiograph or a multi-function electrocardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11407042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for visual evoked response stimulator</td>
<td>A software, which is designed to process data obtained from a visual evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11407052</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for auditory evoked response stimulator</td>
<td>A software for medical device, which is designed to process data obtained from an auditory evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35368012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for auditory-evoked response audiometer</td>
<td>A software for medical device, which is designed to process data obtained from an auditory evoked response audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35747032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electromyograph</td>
<td>A software, which is designed to process data obtained from an electromyograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11474012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electrically-evoked response stimulator</td>
<td>A software for medical device, which is designed to process data obtained from an electrically-evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>32516012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for facial nerve stimulator</td>
<td>A software, which is designed to process data obtained from a facial nerve stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35724012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for somatosensory nerve electrical stimulator</td>
<td>A software, which is designed to process data obtained from a somatosensory nerve electrical stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35726012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for diagnostic neuromuscular electrical stimulator</td>
<td>A software, which is designed to process data obtained from a diagnostic neuromuscular electrical stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35729012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for evoked response computer</td>
<td>A software, which is designed to process data obtained from an evoked response computer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70068012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electronystagmograph</td>
<td>A software, which is designed to process data obtained from an electronystagmograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11479012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electroretinograph</td>
<td>A software, which is designed to process data obtained from an electroretinograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11482012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for visual evoked response computer</td>
<td>A software, which is designed to process data obtained from a visual evoked response computer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70071012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electrooculograph</td>
<td>A software, which is designed to process data obtained from an electrooculograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11480012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nerve function monitor</td>
<td>A software for medical device, which is designed to process data obtained from a nerve function monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36081012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for objective audiometry device</td>
<td>A software, which is designed to process data obtained from an objective audiometry device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11614012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for auditory evoked response audiometer with oto-acoustic emission measurement function</td>
<td>A software for medical device, which is designed to process data obtained from an auditory evoked response audiometer with oto-acoustic emission measurement function. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35747042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nerve locator/stimulator</td>
<td>A software, which is designed to process data obtained from a nerve locator stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35723012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for optokinetic stimulator</td>
<td>A software, which is designed to process data obtained from an optokinetic stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70101012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for carbon dioxide gas analyser</td>
<td>A software, which is designed to process data obtained from a carbon dioxide gas analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31339012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for capnometer</td>
<td>A software, which is designed to process data obtained from a capnometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17148062</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pulse oximeter</td>
<td>A software, which is designed to process data obtained from a pulse oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17148072</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for multi-gas monitor</td>
<td>A software for medical device, which is designed to process data obtained from a multi-gas monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70085012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pulse oximeter</td>
<td>A software, which is designed to process data obtained from a pulse oximeter/capnometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17148082</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for functional oximeter</td>
<td>A software, which is designed to process data obtained from a functional oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70080012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for adult pulmonary function analyser</td>
<td>A software, which is designed to process data obtained from an adult pulmonary function analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35282032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pulmonary exercise stress monitoring system</td>
<td>A software, which is designed to process data obtained from a pulmonary exercise stress monitoring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36146012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for noise generating audiometer</td>
<td>A software, which is designed to process data obtained from a noise generating audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31939012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for visual reinforcement audiometer</td>
<td>A software, which is designed to process data obtained from a visual reinforcement audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>34013012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pure-tone audiometer</td>
<td>A software for medical device, which is designed to process data obtained from a pure-tone audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37503012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for speech audiometer</td>
<td>A software, which is designed to process data obtained from a speech audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>41188012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for audiometer</td>
<td>A software, which is designed to process data obtained from a manually-operated audiometer, automatic-recording audiometer, or computer-controlled audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>41184012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for impedance audiometer</td>
<td>A software, which is designed to process data obtained from an impedance audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36717032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for impedance audiometer with pure-tone and speech audiometric functions</td>
<td>A software for medical device, which is designed to process data obtained from an impedance audiometer with pure-tone and speech audiometric functions. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36717042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for fundus camera</td>
<td>A software, which is designed to process data obtained from a fundus camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>10551012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ophthalmic camera</td>
<td>A software, which is designed to process data obtained from an ophthalmic camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16419012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ultrasound endoscopic observation system</td>
<td>A software, which is designed to process data obtained from an ultrasound endoscopic observation system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70159012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for home use massager</td>
<td>A software, which is designed to process data obtained from a home use electric massager, a home use pneumatically-powered massager, or a home use suction massager. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>34662012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electric massager with needles and a protection pipe</td>
<td>A software, which is designed to process data obtained from an electric massager with needles and a protective pipe. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70979012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software</td>
<td>Details</td>
<td>Approval Number</td>
<td>Approval Category</td>
<td>Applicability</td>
<td>Notes</td>
</tr>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>Software for home use low-frequency therapy equipment</td>
<td>A software, which is designed to process data obtained from home use low-frequency therapy equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70986012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray/CT combined cardiovascular diagnostic X-ray system</td>
<td>A software, which is designed to process data obtained from an X-ray/CT combined cardiovascular diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70003012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for long-term electrocardiographic data recorder</td>
<td>A software, which is designed to process data obtained from a long-term electrocardiographic data recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35162012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ECG recorder with real-time analysis</td>
<td>A software, which is designed to process data obtained from an ECG recorder with real-time analysis. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70063012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for transcutaneous blood gas analyzer</td>
<td>A software, which is designed to process data obtained from a transcutaneous blood gas analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36346012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for oto-acoustic emission instrument</td>
<td>A software, which is designed to process data obtained from an oto-acoustic emission instrument. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36908012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for phonatory function testing equipment</td>
<td>A software, which is designed to process data obtained from phonatory function testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70103012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for cardiac event recorder</td>
<td>A software, which is designed to process data obtained from a cardiac event recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70067012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electroencephalograph</td>
<td>A software, which is designed to process data obtained from an electroencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11467032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment</td>
<td>A software, which is designed to process data obtained from transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17148092</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment</td>
<td>A software, which is designed to process data obtained from transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17148002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for Eustachian tube function testing instrument</td>
<td>A software, which is designed to process data obtained from an Eustachian tube function testing instrument. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70097012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray/CT combined positron CT system</td>
<td>A software, which is designed to process data obtained from an X-ray/CT combined positron CT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70010042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for positron CT combined SPECT system</td>
<td>A software, which is designed to process data obtained from a positron CT combined SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70010052</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for Holter analyser</td>
<td>A software, which is designed to process data obtained from a Holter analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36827012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for powered liquid crystal thermography system</td>
<td>A software, which is designed to process data obtained from a powered liquid crystal thermography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40798012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nuclear medicine system workstation</td>
<td>A software, which configures a nuclear medicine system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40937012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for MRI system workstation</td>
<td>A software, which configures an MRI system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40940012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for diagnostic X-ray imaging system workstation</td>
<td>A software, which configures an X-ray imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40935012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ultrasound imaging system workstation</td>
<td>A software, which configures an ultrasound imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40936012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for general-purpose imaging system workstation</td>
<td>A software, which configures a general-purpose imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70030012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray/CT combined SPECT system</td>
<td>A software, which is designed to process data obtained from an X-ray/CT combined SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70010062</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electronic stethoscope</td>
<td>A software, which is designed to process data obtained from an electronic stethoscope. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>13754012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ECG telephonic transmission equipment</td>
<td>A software, which is designed to process data obtained from ECG telephonic transmission equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70064012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for fetal auditory evoked response stimulator</td>
<td>A software, which is designed to process data obtained from a fetal auditory evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36159012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nasal resistance unit</td>
<td>A software for medical device, which is designed to process data obtained from a nasal resistance unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17228012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for biomechanic platform system</td>
<td>A software, which is designed to process data obtained from a biomechanical platform system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17242012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for laryngostroboscope</td>
<td>A software, which is designed to process data obtained from a laryngostroboscope unit or a laryngostroboscope. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31923012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for nuclear medicine annular SPECT system</td>
<td>A software, which is designed to process data obtained from a nuclear medicine annular SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>40643012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for radionuclide dynamic function testing equipment</td>
<td>A software, which is designed to process data obtained from radionuclide dynamic function testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70008012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for film-recorded digital radiography</td>
<td>A software, which is designed to process data obtained from a film-recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70024012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electronically recorded digital radiography</td>
<td>A software for medical device, which is designed to process data obtained from an electronically recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70025012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for counterpressure sphygmomanometer</td>
<td>A software, which is designed to process data obtained from a counterpressure sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16986012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pressure/pulse wave testing equipment</td>
<td>A software, which is designed to process data obtained from pressure/pulse wave equipment for use in diagnosis. This term may involve the recording media where the software are stored.</td>
<td>70045012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for magnetoencephalograph</td>
<td>A software for medical device, which is designed to process data obtained from a magnetoencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70048012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for thermal dilution cardiac output unit</td>
<td>A software, which is designed to process data obtained from a thermal dilution cardiac output unit and a thermal dilution cardiac output unit with thermal coil. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>10615032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for dye dilution cardiac output calculator</td>
<td>A software, which is designed to process data obtained from a dye dilution cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16177012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for impedance cardiac output unit</td>
<td>A software, which is designed to process data obtained from an impedance cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17496012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for arterial waveform cardiac output unit</td>
<td>A software, which is designed to process data obtained from an arterial waveform cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70050012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pulse contour cardiac output unit</td>
<td>A software, which is designed to process data obtained from a pulse contour cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70051012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for pulse contour cardiac output unitr</td>
<td>A software, which is designed to process data obtained from a sleep assessment device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>33843012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ultrasonic flowmeter</td>
<td>A software, which is designed to process data obtained from an ultrasonic blood flowmeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>10432012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for urodynamic measurement system</td>
<td>A software, which is designed to process data obtained from a urodynamic measurement system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>14307012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for whole body plethysmograph</td>
<td>A software for medical device, which is designed to process data obtained from a whole body plethysmograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35242012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for cardiac stress exercise monitoring system</td>
<td>A software, which is designed to process data obtained from a cardiac stress exercise monitoring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36145012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for ECG and blood pressure Holter recorder</td>
<td>A software, which is designed to process data obtained from an ECG and blood pressure Holter recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70066012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for magnetic stimulator</td>
<td>A software, which is designed to process data obtained from a magnetic stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36902012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for central monitor</td>
<td>A software, which is designed to process data obtained from a central monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>38470012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for noninvasive blood pressure monitor</td>
<td>A software, which is designed to process data obtained from a noninvasive blood pressure monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31681012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for multiparameter monitor</td>
<td>A software for medical device, which is designed to process data obtained from a multiparameter monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>33586012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for respiration monitor</td>
<td>A software, which is designed to process data obtained from a respiration monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35194012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electrocardiographic monitor</td>
<td>A software, which is designed to process data obtained from an electrocardiographic monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35195012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electroencephalographic monitor</td>
<td>A software for medical device, which is designed to process data obtained from an electroencephalographic monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35196012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for transportable multiparameter monitor</td>
<td>A software, which is designed to process data obtained from a transportable multiparameter monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36872012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for intracardiac oximeter</td>
<td>A software for medical device, which is designed to process data obtained from an intracardiac oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>15200012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for invasive blood pressure monitor</td>
<td>A software, which is designed to process data obtained from an invasive blood pressure monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31692012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for telemetry electrocardiograph</td>
<td>A software, which is designed to process data obtained from a telemetry electrocardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>31733012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for telemetry electroencephalograph</td>
<td>A software, which is designed to process data obtained from a telemetry electroencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35626012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for telemetry physiological signal system</td>
<td>A software, which is designed to process data obtained from a telemetry physiological signal system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>32547012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for respiratory resistance meter</td>
<td>A software, which is designed to process data obtained from a respiratory resistance meter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70079032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for powered diagnostic spirometer</td>
<td>A software, which is designed to process data obtained from a powered diagnostic spirometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>13680012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for respiratory function measuring system</td>
<td>A software, which is designed to process data obtained from a respiratory function measuring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>35282042</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for automatic perimeter/ophthalmic camera</td>
<td>A software, which is designed to process data obtained from an automatic perimeter/ophthalmic camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>16918012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for neuropathological diagnostic quantitative sensory tester</td>
<td>A software, which is designed to process data obtained from a neuropathological diagnostic quantitative sensory tester. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37349012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for vestibular function caloric stimulator</td>
<td>A software, which is designed to process data obtained from a vestibular function caloric stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>34891012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electrogustometer</td>
<td>A software, which is designed to process data obtained from an electrogustometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70100012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for body composition analyser</td>
<td>A software for medical device, which is designed to process data obtained from a body composition analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>36022032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for endoscope contour detector device</td>
<td>A software, which is designed to process data obtained from an endoscope contour detector device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70161012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
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<tr>
<td>Software for dental diagnostic intraoral camera</td>
<td>A software for medical device, which is designed to process data obtained from a dental diagnostic intraoral camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70180012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for X-ray bone absorptiometer</td>
<td>A software, which is designed to process data obtained from the following devices: single-energy X-ray bone absorptiometer, single-energy integral X-ray bone absorptiometer, dual-energy X-ray bone absorptiometer, and dual-energy integral X-ray bone absorptiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>37625032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for skin infrared thermometer</td>
<td>A software, which is designed to process data obtained from a skin infrared thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>17888012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for vector cardiograph</td>
<td>A software for medical device, which is designed to process data obtained from a vector cardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>14345012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for electrocardiograph with ultrasonic diagnostic system</td>
<td>A software, which is designed to process data obtained from an electrocardiograph with ultrasound diagnostic system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>11407062</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for eye movement testing equipment</td>
<td>A software, which is designed to process data obtained from eye movement testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>70093012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for surgical navigation unit</td>
<td>A software, which is designed to process data obtained from a surgical navigation unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>38723032</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for MRI-combined positron CT system</td>
<td>A software, which is designed to process data obtained from an MRI-combined positron CT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.</td>
<td>58250012</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Feeding tube supporting system</td>
<td>A device that follows the location of a tip of the intestinal feeding tube inserted into the body and displays the location on a monitor screen in order to support insertion and placement of the feeding tube. It detects magnetism generated from the intestinal feeding tube or from a magnetic field generation unit connected to a stylet inserted in the feeding tube, and follows the location of the tube tip.</td>
<td>59078002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Ozone gas disinfector</td>
<td>A device that disinfects or sterilizes medical devices and medical facilities using ozone gas as a disinfectant to deactivate microorganisms.</td>
<td>46087002</td>
<td>II</td>
<td>15</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use intradermal injection needle SUD</td>
<td>A device with a sharp, hollow needle specifically designed to facilitate and secure the intradermal injection of drugs including vaccines. This device is for single-use.</td>
<td>12745012</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
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<tr>
<td>Description</td>
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<tr>
<td>Stop cock bulb for active device</td>
<td>A device used with a medical tube or pipeline that controls the direction of the flow of a liquid or gas. This product is connected to an active device.</td>
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<tr>
<td>Surporting software for respiratory treatment</td>
<td>A software that collects and stores the treatment information obtained from a ventilator, etc. and assists a physician to assess the treatment effect on the patient, or prepare or change a prescription. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Software for bone density</td>
<td>A software that calculates bone density, etc. in order to obtain bone-related information based on the information collected from CT system, etc. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Surporting software for selecting CL</td>
<td>A software that derives values to establish a standard for contact lenses, etc. based on information collected from a refractometer, a keratometer, a corneal topography system, etc. and supports contact lens selection by a physician. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Surporting software for dental implant treatment</td>
<td>A software that supports preparation of a dental implant treatment plan based on information collected from diagnostic imaging systems in dental implant treatment. This term may involve the recording media where the software are stored.</td>
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</tr>
<tr>
<td>Surporting software for dental orthodontics treatment</td>
<td>A software, that assists diagnosis in orthodontics and supports preparation of an orthodontics plan based on information collected from diagnostic imaging systems in dental orthodontic treatment. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Surporting software for external fixators treatment plan</td>
<td>A software that analyzes information useful for bone fracture and for correction of bone deformities based on information collected from diagnostic X-ray systems, etc. or based on information entered in a therapeutic apparatus, and supports preparation of a treatment plan with external fixators. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Diagnostic supporting software for diabetes</td>
<td>A software that supports analysis and assessment of therapeutic effects of diabetes treatment by processing information collected from a blood glucose meter, etc into the data related to changes or trends in blood glucose levels. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Evaluation software for peripheral blood flow</td>
<td>A software that supports assessment of the presence or absence of impairment of peripheral blood flow, and the severity of the impairment, based on information collected from a rheometer, etc. This term may involve the recording media where the software are stored.</td>
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<tr>
<td>Quantitative calculation software for ICG test</td>
<td>A software that performs quantitative calculation of blood flow in relation to a brightness time change based on information obtained from video images of indocyanine green angiography. This term may involve the recording media where the software are stored. However, it excludes those that correspond to the &quot;software for ultrasonic rheometers.&quot;</td>
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<tr>
<td>Navigation system for intravenous catheter placement</td>
<td>A navigation apparatus for supporting percutaneous insertion and placement of a central intravenous catheter by indicating the direction of movement and the last location of placement of the catheter based on the magnetic field and information about the catheter.</td>
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<tr>
<td>Single-use electrical tissue peeling in general surgery</td>
<td>An electric device used for tissue peeling in general surgery. This device is for single-use.</td>
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<tr>
<td>Physiological signal use motion function improvement supporting system</td>
<td>An active device that exercises the joints based on biological signals to obtain functional improvement.</td>
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</tr>
<tr>
<td>Product Description</td>
<td>Description</td>
<td>Code</td>
<td>Grade</td>
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<td>②</td>
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<tr>
<td>Safety valve for heart-lung bypass</td>
<td>A safety valve, which is one of the components of a heart-lung bypass system, connected to the blood delivery side of the centrifugal pump when the pump is operated, to prevent blood regurgitation from occurring in association with stopping of centrifugal pump operation. This device is for single-use.</td>
<td>17581012</td>
<td>II</td>
<td>2①</td>
<td></td>
</tr>
<tr>
<td>Single-use auxiliary tool for valvuloplasty</td>
<td>A surgical device used in valvuloplasty. It is used as a template when an artificial tendinous cord is formed. This device is for single-use.</td>
<td>71053002</td>
<td>II</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Single-use guides for automatic suture</td>
<td>A device that is connected to an automatic suture device and guides the needle to the correct location, such as the dorsal side of the cleavage site, without causing damage to the vessel. This device is for single-use.</td>
<td>71054002</td>
<td>II</td>
<td>6,7</td>
<td></td>
</tr>
<tr>
<td>Washing catheter for bronchoalveolar lavage</td>
<td>A flexible tube used for specimen collection from bronchoalveolar lavage fluid.</td>
<td>32158002</td>
<td>II</td>
<td>5②</td>
<td></td>
</tr>
<tr>
<td>Analyzing software for hemodynamics or cardiac function</td>
<td>A medical device program that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc. and uses the results for diagnosis. This term may involve the recording media where the software are stored.</td>
<td>61213002</td>
<td>II</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Collimator for motorized manual aperture control diagnostic X-ray system</td>
<td>A system used to prevent scatter or leakage of a drug including carcinostatic agent from environment by connecting containers when transferring the drug from one container to another drug solution container. It has a mechanism to control the differential pressure of inside and outside the container.</td>
<td>71055002</td>
<td>II</td>
<td>2①</td>
<td></td>
</tr>
<tr>
<td>Collimator for non-motorized manual aperture control diagnostic X-ray system</td>
<td>An electric device used to pressurize the middle ear by air vibration. This device is mainly used by the patient at home under the direction of a doctor, to reduce vertiginous attack arised from delayed endolymphatic hydrops or Ménière's disease.</td>
<td>47542002</td>
<td>II</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Diagnostic assistant device for pathological whole slide image</td>
<td>A device used to process the pathological images that assist pathological diagnosis and support preparation of a treatment plan through the storage, display, and capture of high magnification images of whole pathological slide samples (pathological whole slide images).</td>
<td>15132012</td>
<td>II</td>
<td>10</td>
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<tr>
<td>Medical Device Type</td>
<td>Description</td>
<td>Category Code</td>
<td>Rating</td>
<td>Applicability</td>
<td></td>
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<tr>
<td>Cranial reshaping orthotic helmet</td>
<td>A helmet-shaped device used to correct deformed cranial bone of infant. It is designed and manufactured to fit an individual patient.</td>
<td>62265003</td>
<td>II</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Rectal plug</td>
<td>A device inserted into the rectum via the anus, to prevent leakage of intestinal contents to the outside the body. It is used for a patient with fecal incontinence or gas incontinence.</td>
<td>46193002</td>
<td>II</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Metal material for dental three-dimensional additive manufacturing</td>
<td>A metal material for three-dimensional additive manufacturing mainly used for fabrication of dental restorations and appliances.</td>
<td>71060002</td>
<td>II</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Artificial nose for inhalational anesthetic administration</td>
<td>A passive, non-active, canister-shaped apparatus used to administer the vaporized inhalational anesthetic via inspiratory air in addition to remove foreign bodies and captures and use heat and moisture in exhaled air to heat and humidify inspiratory air when it is connected in line with the patient's artificial airway.</td>
<td>71064002</td>
<td>II</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Load sensor unit for artificial joint replacement</td>
<td>An instrument used to assist surgeon during artificial joint replacement. Usually it consists of sensor computer system, etc., and the sensor is placed directly into a surgical site during surgery. It displays the location of loads and dynamics in proportion to the level of movement.</td>
<td>58988002</td>
<td>II</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Invasive head fixation device for neurosurgery</td>
<td>A device used for fixation or support the patient's head during a neurosurgical surgery or radiotherapy. It is equipped with functions to perform procedure such as stereoecephalotomy with precision. It consists of a frame to which surgical device, etc. are attached, and bolts to fix the patient's head invasively to the frame.</td>
<td>35361002</td>
<td>II</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Description</td>
<td>Detailed Description</td>
<td>Code</td>
<td>Class</td>
<td>Use Level</td>
<td>Applicable</td>
</tr>
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<td>-----------------------------------------------------------------------------------</td>
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<tr>
<td>Eyelid heating pressure device</td>
<td>A device used to heat or pressurize on the eyelid with, for instance, electric heat or air pressure.</td>
<td>71072002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Supporting software for root canal</td>
<td>A software for medical device, which is used to support preparation of a treatment plan</td>
<td>71073002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Analyzer for hemodynamics or cardiac function</td>
<td>A device that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc., and uses the result for diagnosis.</td>
<td>71075002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>ICG fluorescence imaging view box</td>
<td>A device used in fluorescence imaging offered to make a diagnosis, etc. during indocyanine green angiography. Some have a near infrared camera to take fluorescent images or device for projecting contrast images.</td>
<td>71076002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Retinal scanning laser glasses</td>
<td>A device that corrects vision by scanning retina and projecting images onto the retina using laser light. For example, it consists of a light source that outputs laser light and an optical scanning unit that scans the retina with laser light.</td>
<td>71079002</td>
<td>II</td>
<td>9</td>
<td>applicable</td>
</tr>
<tr>
<td>Supporting software for detecting lesion with endoscopic imaging</td>
<td>A software, which is designed to process data obtained from endoscopic image. The resultant data are provided for diagnostics, etc. It has a function for detecting lesion candidates. This term may involve the recording media where the software are stored.</td>
<td>71080002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed cuff for pneumatically-powered massager</td>
<td>A cuff for a pneumatically-powered massager used for the non-invasive treatment of venous disorders. The device facilitates venous blood flow by applying stimuli that stimulate muscle contraction. It is used to apply counter pressure to the arms or legs of patients. Usually, the device is used for the treatment of leg edema. The device is a single-chamber, pneumatic stocking system. The entire chamber regularly inflates and deflates to provide rhythmic compression of a limb. This product is a reprocessed single-use device of cuff for pneumatically-powered massager that is intended to be used only once.</td>
<td>71084002</td>
<td>II</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Pelvic-organ-supporting pessary</td>
<td>A circular device made of silicone or plastic material, etc. that is placed in the vagina and used to mechanically support pelvic organs. This may be a reusable device.</td>
<td>34149002</td>
<td>II</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed single-use natural orifices endoscopic dilator</td>
<td>A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. Dilation is performed from a natural orifice of the human body, in the urethra or urinary tract, for example. It is a flexible or rigid rod or tube. This product is a reprocessed single-use device.</td>
<td>38821102</td>
<td>II</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Visual field securing gel for natural orifices endoscope</td>
<td>A transparent gel that secures the visual field during endoscopic treatment or endoscopy by being injected through an endoscope inserted into a natural orifice of the human body. It assists endoscopic viewing and intervention.</td>
<td>71085002</td>
<td>II</td>
<td>5-②</td>
<td>applicable</td>
</tr>
<tr>
<td>Design support software for dental restorations</td>
<td>A software, which supports design of dental restorations by a dentist based on information collected from diagnostic imaging systems, etc. This term may involve the recording media where the software are stored.</td>
<td>50484002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Smoking cessation treatment support system</td>
<td>A system that includes an analyzer for measuring expired carbon monoxide concentration and a software that assists smoking cessation treatment by promoting behavioral modification.</td>
<td>71087002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
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<table>
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<tr>
<th>Product Description</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Quantity</th>
<th>Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software for home use electrocardiograph</td>
<td>A software for home use, which is designed to process ECG information obtained from general-purpose devices. The resultant data are provided for supporting the detection of signs of disease. This term may involve the recording media where the software are stored.</td>
<td>47699002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Software for home use heart rate monitor</td>
<td>A software for home use, which is designed to process heart rate information obtained from general-purpose devices. The resultant data are provided for supporting the detection of signs of disease. This term may involve the recording media where the software are stored.</td>
<td>58884002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Amyloid β mass spectrometry set</td>
<td>A set of mass spectrometry testing that measures peptides (amyloid β peptides, etc.) derived from amyloid precursor proteins from samples of biological materials. It consists of pretreatment reagents and analyzing software.</td>
<td>71088002</td>
<td>II</td>
<td>10</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed thoracic trocar</td>
<td>A surgical device with a sharp pyramidal or conical tip used to puncture the body cavity during chest surgery. A trocar assembly can be introduced in combination with a compatible sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working channel into the body cavity. This product is a reprocessed single-use device.</td>
<td>70218002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed single-use trocar sleeve</td>
<td>A plastic sleeve used together with a trocar during puncture of a body cavity. Removing the trocar after puncture creates a working channel into the body cavity. The sleeve may have a shut-off valve or port for supplying gas or liquid. Some products do not require a trocar for use. The sizes and designs vary. The sleeve comes with accessories that are required for it to function. This product is a reprocessed single-use medical device.</td>
<td>61813002</td>
<td>II</td>
<td>6</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed abdominal trocar</td>
<td>A surgical device with a sharp pyramidal or conical tip used to puncture the abdominal wall. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after the puncture creates a working channel into the body cavity. This product is a reprocessed single-use device.</td>
<td>61814002</td>
<td>II</td>
<td>7</td>
<td>applicable</td>
</tr>
<tr>
<td>Reprocessed reducer for trocar</td>
<td>A device to be attached to a trocar sleeve. It reduces gas leakage during the procedure, and keeps the body cavity airtight. This product is a reprocessed single-use device.</td>
<td>70225002</td>
<td>II</td>
<td>—</td>
<td>applicable</td>
</tr>
<tr>
<td>Probe cover for body surface ultrasonic</td>
<td>A device applied to an ultrasonic probe to protect it from body fluid and dirt when the probe is used on the body surface. It includes a device applied to the ultrasonic probe to confirm the insertion direction of puncture needle, or a device used for attaching instruments for guiding the insertion direction of puncture needle to the ultrasonic probe or the like.</td>
<td>70014000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Gridd for MRI</td>
<td>A grid used for position the puncture site etc. when biopsying under the magnetic resonance imaging (MRI) guide.</td>
<td>70022000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
</tbody>
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N/A
<table>
<thead>
<tr>
<th>Description</th>
<th>Note</th>
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</thead>
<tbody>
<tr>
<td>Collimator for motorized automatic aperture control diagnostic X-ray system</td>
<td>A beam forming/limiting device equipped with a shutter system with an automatic control motor. It is designed to adjust the shutter and limit the X-ray beam to the size of the film cassette in the holder. A collimator assembly can be attached to the beam emission port of the X-ray tube housing assembly. Generally, it is equipped with a light localizer which projects a light field consistent with the X-ray beam onto the patient's body, and places the X-ray tube on the center of the film cassette. The X-ray collimator reduce the impact of scattered radiation that could affect the quality of image, and to protect patients, it inhibits or eliminates the radiation reaching body parts other than the target site.</td>
</tr>
<tr>
<td>Collimator for motorized manual aperture control diagnostic X-ray system</td>
<td>A X-ray beam forming/limiting device equipped with a motor-equipped shutter/length control system. The operator should manually adjust the length of the collimator shutter or the cone, and limit the size and the configuration of X-ray beam to the size of the X-ray cassette to be used prior to irradiation. Most of the motor-equipped collimator assemblies are equipped with a light localizer. The X-ray collimator reduce the impact of scattered radiation that could affect the quality of image, and to protect patients, it inhibits or eliminates the radiation reaching body parts other than the target site.</td>
</tr>
<tr>
<td>Collimator for non-motorized manual aperture control diagnostic X-ray system</td>
<td>A X-ray beam limiting device without a motor. Aperture size/length/shutter assembly should be manually adjusted to limit the size of the X-ray beam to the size of the X-ray cassette to be used. The device has been designed to allow manual control to operate more than a pair of shutters. It has also been designed to allow the addition or removal of an accessory device and an extension device so that the operator can change the size and configuration of the beam irradiated from the cone and cylinder. The X-ray collimator reduce the impact of scattered radiation that could affect the quality of image, and to protect patients, it inhibits or eliminates the radiation reaching body parts other than the target site.</td>
</tr>
<tr>
<td>X-ray tube support floor stand</td>
<td>A hardware assembly consisting of a floor support stand and associated mechanical, electronic, or software control. It constitutes the structure used for installation, retention, and position adjustment of the X-ray tube device, an accessory of the X-ray device designed for diagnostic X-ray, a therapeutic X-ray device, and a device for positioning the radiotherapy plan. Some are designed to support the radiation cassette or image receptor assembly, and adjust the movement and position to the position of X-ray tube (e.g., C-arm assembly). This device group is categorized as parts or accessories of the X-ray device.</td>
</tr>
<tr>
<td>Ceiling mount X-ray tube support</td>
<td>A ceiling-mounted metal fitting assembly and associated mechanical, electronic, or software control. It constitutes the structure used for the installation, retention, and position adjustment of the X-ray tube device, an accessory of the X-ray device designed for diagnostic X-ray, a therapeutic X-ray device, and a device for positioning the radiotherapy plan. Some are designed to support the radiation cassette or image receptor assembly, and adjust the movement and position to the position of X-ray tube (e.g., C-arm assembly).</td>
</tr>
<tr>
<td>Wall mounting X-ray tube support</td>
<td>A wall-mounted metal fitting assembly and associated mechanical, electronic, or software control. It constitutes the structure used for the installation, retention, and position adjustment of the X-ray tube device, an accessory of the X-ray device designed for diagnostic X-ray, a therapeutic X-ray device, and a device for positioning the radiotherapy plan. Some are designed to support the radiation cassette or image receptor assembly, and adjust the movement and position to the position of X-ray tube (e.g., C-arm assembly).</td>
</tr>
<tr>
<td>Non-powered patient table for general-purpose diagnostic X-ray system</td>
<td>A non-electric patient platform equipped with a fixed posture table or non-electric patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. This is designed to adjust and keep the patient's general/planar images that require a general-purpose X-ray device and diagnostic equipment.</td>
</tr>
<tr>
<td>Powered patient table for general-purpose diagnostic X-ray system</td>
<td>A programmable electric patient platform which is designed to adjust and keep the patient's posture when taking general/planar images that require a general-purpose X-ray device and special diagnostic photography. It is equipped with an electronic control or software control function that controls the height and position of the table. It is either fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation.</td>
</tr>
<tr>
<td>Non-powered patient table for fluoroscopic diagnostic X-ray system</td>
<td>A non-electric patient platform equipped with a fixed posture table, or a non-electric patient platform equipped with mechanical table top positioning control and table height control such as a pneumatic control magnetic lock, crank, and lever. Designed to position and keep the patient's posture for imaging or intervention that requires a general-purpose X-ray fluoroscopy system. It is either fixed, movable, or incorporated into the design of the general-purpose X-ray system. The device is used only for X-ray image diagnosis.</td>
</tr>
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<td>Model Description</td>
<td>Description</td>
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</tr>
<tr>
<td>Powered patient table for fluoroscopic diagnostic X-ray system</td>
<td>A electrically powered patient table to position and keep the patient's posture for imaging or intervention that requires a general-purpose X-ray fluoroscopy system. A programmable electric patient platform equipped with an electronic control or software control function that controls the position, height and movement of the table relative to the X-ray beam. Some are fixed, movable, or incorporated into the design of the general-purpose X-ray fluoroscopy system. The device is used only for X-ray image diagnosis.</td>
</tr>
<tr>
<td>Non-powered patient table for bedside diagnostic X-ray system</td>
<td>A type of non-electric patient bed equipped with a mattress that serves as an X-ray table for bedside X-ray photography. Generally, it is used for controlling severely ill patients and for intensive treatment. Some are equipped with a fixed posture table, and others are equipped with a mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Made of radiotranslucent materials with a low X-ray attenuation coefficient and equipped with a special design that allows movement of the table relative to the X-ray beam.</td>
</tr>
<tr>
<td>Powered patient table for bedside diagnostic X-ray system</td>
<td>A type of programmable electric patient bed equipped with a mattress that serves as an X-ray table for bedside X-ray photography. Generally, it is used for controlling severely ill patients and for intensive treatment. It is specifically designed to allow bedside X-ray photography for various types of imaging and easy installation of the C-arm, an opening and a mattress. Some are equipped with an electronic control or software control function that controls the height and position of the bed. Generally movable. The bedhead and the bed are designed to position and keep the patient's posture for examinations of the heart and blood vessels or intervention that requires an X-ray angiography device.</td>
</tr>
<tr>
<td>Non-powered patient table for planar tomography diagnostic X-ray system</td>
<td>A non-electric patient platform equipped with a fixed posture table, or a non-electric patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to position and keep the patient's posture for plane tomography. Either fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient.</td>
</tr>
<tr>
<td>Powered patient table for planar tomography diagnostic X-ray system</td>
<td>A programmable patient platform for electric X-ray mammography which is equipped with an electronic control or software control function that controls the height and position of the table. It is designed to position and keep the patient's posture for plane tomography. Either fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient.</td>
</tr>
<tr>
<td>Non-powered patient table for cardiovascular diagnostic X-ray system</td>
<td>A non-electric patient platform equipped with a fixed posture table, or a non-electric patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to position and keep the patient's posture for examinations of the heart and blood vessels or intervention that requires an X-ray angiography device. Various accessories used for treatment of the heart and other organs (e.g., brain and kidney angiography and intervention under angiography) can be incorporated. Fixed or movable patient platform is available.</td>
</tr>
<tr>
<td>Powered patient table for cardiovascular diagnostic X-ray system</td>
<td>A programmable electric patient platform equipped with electronic control or software control function that controls the position, height and movement of the table relative to the X-ray beam. Designed to position and retain the patient's posture for examinations of the heart and blood vessels or intervention that requires an X-ray angiography device. Various accessories used for treatment of the heart and other organs (e.g., brain and kidney angiography and intervention under angiography) can be incorporated. Fixed or movable patient platform is available.</td>
</tr>
<tr>
<td>Non-powered patient table for X-ray mammography system</td>
<td>A non-electric patient platform equipped with a fixed posture table top or a non-electric patient platform equipped with mechanical table top positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to adjust and keep the patient's posture for X-ray mammography. Fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient. Some are designed to incorporate various accessories such as an orientation device and other posture fixtures, film holder, cassette, and dosimeter.</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
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<td>-----------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Powered patient table for X-ray mammography system</td>
<td>A programmable patient platform for electric X-ray mammography is equipped with electronic control or software control that controls the height and position of the table top, and designed to adjust and keep the patient's posture for X-ray mammography. Fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient. Generally, equipped with special openings and metal clamps for mammography.</td>
</tr>
<tr>
<td>X-ray image intensifier</td>
<td>An X-ray image intensifier that converts an X-ray image into an optical image, and further into an electron image, and finally into a size-reduced brightness optical image. It consists of a large vacuum glass container equipped with 4 fundamental sub-systems. The sub-systems comprise an input fluorescent body/fluorescent X-ray screen.</td>
</tr>
<tr>
<td>X-ray television system</td>
<td>A TV camera designed to capture image output using an output fluorescent body of an X-ray image intensifier. It consists of image sensor elements and an electronic circuit, and converts optical images into analog signals or digital signals, etc. Mainly used for a general-purpose fluoroscopic diagnostic device and cardiovascular fluoroscopic diagnostic device.</td>
</tr>
<tr>
<td>X-ray fluoroscopy image recording system photospot camera</td>
<td>A photo camera with an installation/support structure and film magazine designed to directly capture images on photosensitive film from the output fluorescent body of an image intensifier of an X-ray fluoroscopy system. Most photo spot cameras are able to advance frames at short intervals while continuously taking a certain number of images. Generally, 70, 90, or 105 mm film is used.</td>
</tr>
<tr>
<td>Cinefluorographic X-ray fluoroscopy image recording system</td>
<td>A sub-system of an X-ray fluoroscopy system that uses a movie or video camera designed to record continuous X-ray fluoroscopic images using a cinefluorography system, on movie film (Generally 16 mm or 35 mm film) or other media. The cinefluorography system is part of an X-ray fluoroscopy system, and consists of a cinefluorography system (movie camera or video camera), an optomechanical device, film, a developing processor, a projector, and electric machine control video display software.</td>
</tr>
<tr>
<td>X-ray indirect roentgenography camera</td>
<td>A device that converts a subject's fluorescence image generated on the fluorescent plate by X-rays into a reduced image on fluoroscopic film using a mirror and lens.</td>
</tr>
<tr>
<td>X-ray flat panel detector</td>
<td>An X-ray detector with a planar X-ray entry face that detects X-rays that pass through the body and converts them into electric signals. The entering X-rays are absorbed by a fluorescent body or photoconductor, converted into electric signals by pixels inside, and digitally output sequentially. The detector is smaller than an electron tube detector, and characterized by its planar entry face.</td>
</tr>
<tr>
<td>Equipment Type</td>
<td>Description</td>
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</tr>
<tr>
<td>Liquid crystal thermography sheet</td>
<td>A non-electric device that generates, displays and analyzes images and graphs of body surface temperature distribution in order to diagnose and evaluate various conditions and symptoms. Sheets made of cholesteric liquid crystal-based material is buried in the outer layer of a blanket, pillow and mattress that surround the body. The material changes its color in response to changes in the temperature of the body surfaces that are in contact.</td>
</tr>
<tr>
<td>Automatic X-ray film changer</td>
<td>An automatic X-ray film changer is generally one of the components of a diagnostic X-ray device. It is designed to send a cassette, a sheet of X-ray film, or a film roll having a specific size from a supply magazine to a pair of sensitization screens for exposure, and then send it to the receiving bin. Some are controlled by an electric machine or software. Typical main components of an automatic changer for sheet film or roll film include a cassette holder, installation stand, control panel, change mechanism, supply magazine, receiving magazine, control, program selector and other components.</td>
</tr>
<tr>
<td>Bucky device</td>
<td>A device that effectively absorbs scattered X-ray film emitted from an X-ray film subject (patient) by using a grid, and eliminates the stripes by moving the grid to improve the quality of images in diagnostic X-ray photography. The device consists of the main case, grid, grid transfer mechanism and a cassette tray.</td>
</tr>
<tr>
<td>Motorized diagnostic imaging view box</td>
<td>A device equipped with an electric mechanical or software controlled motor that retains, retrieves, and projects light for direct observation of medical images taken using a variety of methods such as X-ray, magnetic resonance (MR), CT, and ultrasound, and recorded in radiographic film. The motor-equipped observation device also known as a...</td>
</tr>
<tr>
<td>Non-motorized diagnostic imaging view box</td>
<td>A non-motorized device that retains, fixes, and projects light for medical images taken using a variety of methods such as X-ray, magnetic resonance (MR), CT, ultrasound, or nuclear medicine, and recorded in films. A simple structure without a motor, it is mounted on the wall or placed on a table. It provides bright even illumination, and comes with film...</td>
</tr>
<tr>
<td>Diagnostic imaging view box with densitometer</td>
<td>A device to assist interpretation of medical images recorded on X-ray film, and analyzes film density information. The device consists of a film transportation system, stabilized light source, CCD sensor and other optical systems and photoelectric conversion sensors. The device reads bone contrast information from the film, and measures partial bone density.</td>
</tr>
<tr>
<td>Darkroom automatic radiographic film developer</td>
<td>An automatic film development device that requires manual removal of X-ray film or radiographic film from a cassette and manual installation into a development device in a darkroom. The device is designed to send X-ray film or radiographic film to the liquid developer, and does not require any work other than inserting the film in the film development process. Generally, the device consists of 6 main sub-systems – i.e., controls for film transfer, temperature, circulation, supplementation, drying, and electricity.</td>
</tr>
<tr>
<td>Darkless automatic radiographic film developer</td>
<td>A bright room development device designed to eliminate the need for a darkroom. The automatic development device is for X-ray film or radiographic film. It automatically loads unused film into a cassette, and sends used film into the automatic film developer of the device. The device consists of the following 6 main sub-systems – i.e., controls for film transfer, temperature, circulation, supplementation, drying, and electricity – as well as a cassette loader and unloader. Generally, it is designed to be installed on the floor or desk.</td>
</tr>
<tr>
<td><strong>Automatic cine film radiographic film developer</strong></td>
<td>An automatic photographic film development device for 16 mm or 35 mm film rolls used for X-ray fluoroscopic examination (cinefluorography) which are necessary for a movie camera that records the fluorescent body discharged from an image intensifier as a continuous X-ray fluoroscopic image in movie format. Also known as a cine film development device.</td>
</tr>
<tr>
<td><strong>Automatic film developing processor for dental X-Ray film</strong></td>
<td>An automatic Dental X-ray film developing processor. Manual types are excluded.</td>
</tr>
<tr>
<td><strong>Multi-format diagnostic imaging camera</strong></td>
<td>Usually, a camera-based image device that adopts a laser scanning technique. The device captures digital images generated using image diagnosis systems such as CT, MRI, PET, gamma camera, and ultrasound, and reproduces the captured digital image on film in various image formats. It is usually equipped with a function that allows the operator to designate the number of images recorded on one film (multi-formatting). Usually, 1 to 128 images in even numbers can be selected for the number of images recorded on one film.</td>
</tr>
<tr>
<td><strong>Diagnostic imager</strong></td>
<td>An image diagnostic imager captures digital image signals such as CT, MRI, ultrasound, and CR, and reproduces the captured images on image recording film. The image is reproduced on film using a laser beam, or thermal head. The imager generally consists of the image signal processor, a laser scanner and a film developer etc. The multiple image information can be recorded on one film.</td>
</tr>
<tr>
<td><strong>X-ray exposure reduction device</strong></td>
<td>An X-ray control function that is intended to reduce X-ray exposure, including a pulse fluoroscope. It provides an auxiliary function added to an X-ray control device as the component.</td>
</tr>
<tr>
<td><strong>X-ray automatic exposure control</strong></td>
<td>An automatic exposure controller is a software control or electronic control sub-system of a diagnostic X-ray system. It automatically monitors X-ray beams that pass through the body during an examination, and terminates the irradiation when radiation reaches the density sufficient for radiation imaging.</td>
</tr>
<tr>
<td>Patient positioning device for head/neck</td>
<td>A device that consists of fixed or adjustable positioning devices such as frames and plates, and is specifically designed to properly position and fix the patient's head, neck, and cervical spine for image diagnosis and dental X-ray photography. In image-guided surgery, interventional therapy, or radiotherapy, the device is used to easily implement reproducible positioning for continuous image examination or continuous radiotherapy as necessary.</td>
</tr>
<tr>
<td>Patient positioning device for breast</td>
<td>A device that is specifically designed to properly position and fix a female patient's breasts and chest for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device may come in frames or plates, and is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.</td>
</tr>
<tr>
<td>Patient positioning device for extremity</td>
<td>A device that is specifically designed to properly position and fix a patient's arms and legs for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device may come in frames or plates, and is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.</td>
</tr>
<tr>
<td>Patient positioning device for pelvis</td>
<td>The device that consists of frames, plates, or other parts, and is specifically designed to properly position and fix the patient's abdomen and pelvic region for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device is also used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.</td>
</tr>
<tr>
<td>Patient positioning device for whole body</td>
<td>A device that consists of fixed or adjustable parts (e.g., frames and plates), and is specifically designed to properly position and fix the patient's whole body for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device is also used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.</td>
</tr>
<tr>
<td>X-ray fluorescent screen</td>
<td>A fluorescent screen for an X-ray device and is one of the component of an X-ray fluoroscopy system, and used to allow the observer to directly observe an X-ray image of the patient in real time. It is similar to X-ray intensifying screens, and just like intensifying screen, it consists of relining materials (cardboard, plastic, or metal), reflection layer materials such as titanium dioxide, active layers (calcium tungstate, barium sulfate, or rare-earth materials) and protective layers of the fluorescent body. The light emitted for image formation should have wavelengths that can be seen by the human eye.</td>
</tr>
<tr>
<td>Photo-stimulable fluorescent screen</td>
<td>A fluorescent screen that stores X-ray energy, and generates fluorescence equivalent to the energy by irradiation of laser beam. Some photostimulable fluorescent screens are combined with a cassette. Usually, the screen is used in combination with a computed radiograph, and a cassette for a photostimulable fluorescent screen.</td>
</tr>
<tr>
<td><strong>X-ray intensifying screen</strong></td>
<td>A device generally considered as a component of an X-ray film cassette used for X-ray image diagnosis. Used concurrently with emulsion X-ray film. The device consists of a reflecting material (cardboard, plastic, or metal), a reflection layer made of such materials as titanium dioxide, an active layer made of a fluorescent body (calcium tungstate, barium sulfate, or rare earth), and a protective layer (generally, plastic coating) that prevents static electricity and allows cleaning. It is used to reduce the exposure dose to the patient and shorten the exposure period to minimize motion artifacts on film images.</td>
</tr>
<tr>
<td><strong>Manually-operated X-ray film cassette</strong></td>
<td>A tool that seals X-ray film and protects it from exposure to room lights when transported to and inserted into an image diagnostic device, film formatting device, or film development device for medical imaging. Generally, it is designed to be used in combination with a specific imaging device and image formatting unit, and consists of a relining material (cardboard, plastic, or metal), a reflection layer made of such materials as titanium dioxide, an active layer made of a fluorescent body (calcium tungstate, barium sulfate, or rare earth), and a protective layer (generally, plastic coating) that prevents static electricity and allows cleaning. It is used to reduce the exposure dose to the patient and shorten the exposure period to minimize motion artifacts on film images.</td>
</tr>
<tr>
<td><strong>Automatic film changing X-ray film cassette</strong></td>
<td>An X-ray film cassette designed to be used with an automatic X-ray film changer, and function as a part of the film changer. The cassette is, under specified darkroom conditions, loaded with X-ray film, and attached to the loading magazine of the film changer. The cassette remains inserted into the magazine after exposure until detached by the operator for final processing.</td>
</tr>
<tr>
<td><strong>Photo-stimulable fluorescent screen cassette</strong></td>
<td>A photostimulable fluorescent screen cassette used for X-ray photography. Usually, it is concurrently used with a computed radiograph, or a photostimulable fluorescent screen.</td>
</tr>
<tr>
<td><strong>X-ray grid</strong></td>
<td>A stationary or moving (reciprocating or rotating) grid used for diagnostic X-ray photography such as plain X-ray imaging and mammography. Generally, it consists of a housing (box) that is divided by radiotranslucent spacers (intermediates) and which is filled with aluminum or radiotranslucent organic compounds, and contains pieces of lead that absorb scattered X-rays, reduce artifacts, and improve the contrast of X-ray images.</td>
</tr>
<tr>
<td><strong>Stationary X-ray grid</strong></td>
<td>A component of an X-ray device used for diagnostic X-ray photography such as plain X-ray imaging and mammography. Generally, it consists of a housing (box) that is divided by radiotranslucent spacers (intermediates), and contains pieces of lead foil. These spacers (intermediates) are filled with aluminum or radiotranslucent organic compounds. An X-ray photography grid is placed between the X-ray subject (patient) and the X-ray film, and it absorbs scattered X-rays, reduces artifacts, and improves the contrast of X-ray images.</td>
</tr>
<tr>
<td><strong>Moving X-ray grid</strong></td>
<td>A component of an X-ray device used for diagnostic X-ray photography. The moving grid is designed to automatically move back and forth in linear or reciprocal movement during one X-ray irradiation or continuous irradiation. Generally, it consists of pieces of lead foil divided by radiotranslucent spacers (intermediates). It is used to absorb scattered X-rays, minimize artifacts, and improve the contrast of X-ray images. Some are designed to move continuously during a series of X-ray irradiations. This continuous rotational motion erases shadows caused by lead pieces. It is used to absorb scattered X-rays, reduce artifacts, and improve the contrast of X-ray images.</td>
</tr>
<tr>
<td><strong>Rotating X-ray grid</strong></td>
<td>A component of an X-ray device used for diagnostic X-ray photography. The rotating X-ray grid is mainly used for continuous photography. It is designed to rotate automatically and continuously during a series of X-ray irradiations. This continuous rotational motion erases shadows caused by lead pieces. It is used to absorb scattered X-rays, reduce artifacts, and improve the contrast of X-ray images. It consists of a circular structure with</td>
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<td>Description</td>
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<tr>
<td>Dental X-ray beam alignment device</td>
<td>A mechanical device used to support and place dental X-ray film. In the case of dental X-ray imaging, it is used as a guide for proper physical positioning of the X-ray tube relative to the placed dental X-ray film. Some are designed to serve as a guide for a dental X-ray device used inside or outside the oral cavity.</td>
</tr>
<tr>
<td>Dental digital X-ray sensor</td>
<td>An intraoral digital dental X-ray sensor used in combination with a general-purpose dental X-ray imaging device. This category excludes a sensor equipped with a sensor driving circuit or signal processing circuit, and a sensor connected to an active medical device.</td>
</tr>
<tr>
<td>Screen medical X-ray/diagnostic imaging film</td>
<td>An X-ray film designed for medical imaging. The film is sensitive to the wavelengths of the light emitted from an intensifying screen or other visible light sources. It is a sheet coated with a photosensitive emulsion composed of particles having sensitivity to light.</td>
</tr>
<tr>
<td>Non-screen medical X-ray/diagnostic imaging film</td>
<td>A non-screen type X-ray film designed for medical imaging. Non-screen type films are designed to be exposed directly to X-rays. The sensitivity to visible light emitted from an intensifying screen is relatively low. It is a sheet coated with a photosensitive emulsion.</td>
</tr>
<tr>
<td>Diagnostic imaging cine film</td>
<td>A movie or movie film in various sizes (e.g., 16 mm, 35 mm) specifically designed for medical or dental image diagnosis. In medical image diagnosis, film of this type is often called cine-film.</td>
</tr>
<tr>
<td>Non-self-developing diagnostic imaging film</td>
<td>A sheet or roll of film (e.g., 70 mm, 90 mm, 100 mm, or 105 mm) specifically designed for medical or dental image diagnosis. A film of this type requires a photo developer in order to develop the images captured in the film.</td>
</tr>
<tr>
<td>Self-developing diagnostic imaging film</td>
<td>Self-developing photographic films (e.g., instant, Polaroid) specifically designed for medical or dental image diagnosis, which is used with a dedicated camera, and in particular, for the cases where it is useful to confirm whether the obtained result exactly reflects the situation.</td>
</tr>
<tr>
<td>Screen dental diagnostic imaging X-ray film</td>
<td>Screen-type X-ray film of a predetermined size to be used specifically for a dental X-ray device. Screen-type films are designed to be sensitive mainly to the wavelength of light emitted from an intensifying screen. It is a sheet made of a single-sided (single-sided emulsion film) or dual-sided (dual-sided emulsion film) transparent film base made of hydrogenic material.</td>
</tr>
<tr>
<td>Non-screen dental diagnostic imaging X-ray film</td>
<td>Non-screen type X-ray film of a predetermined size to be used specifically for a dental X-ray device. The non-screen type film is designed to be exposed directly to X-rays, and has relatively weak photosensitivity to visible light emitted from an intensifying screen. It is a sheet made of a single-sided (single-sided emulsion film) or dual-sided (dual-sided emulsion film) transparent film base made of hydrogenic material.</td>
</tr>
<tr>
<td>Radiation protection apron</td>
<td>A standard length or half-length apron to protect the patient, the operator, and other personnel from radiation exposure during a medical or dental procedure. Some have a fixed or removable collar to protect the neck and thyroid. The apron generally consists of a liquid resistant outer cover that covers a thin sheet made of lead or other materials comparable to lead. For neutron attenuation, the apron is made of hydrogenic materials. For use in beta/gamma-mixed radiation fields, the apron is made of layers of a hydrogenic material and a materials comparable to lead.</td>
</tr>
<tr>
<td>Radiation protection bib</td>
<td>A personal protection device that protects the chest of the patient, the operator, and other personnel from unnecessary radiation exposure during a medical/dental procedure for diagnosis and treatment. Some have a fixed or removable collar to protect the neck and thyroid.</td>
</tr>
<tr>
<td>Radiation protection gloves</td>
<td>A personal protection device that completely protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. Each finger is individually protected. Generally, the gloves used for diagnostic X-ray and nuclear medicine consist of</td>
</tr>
<tr>
<td>Radiation protection mitten</td>
<td>A personal protection device that protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. The mittens are also called mitts, and protect the thumb and other fingers individually or together. Generally, the mittens used for</td>
</tr>
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<td>Category</td>
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<tr>
<td>Partial hand radiation protector</td>
<td>A flat pad with straps or partial gloves that protect part of hands and fingers from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. Generally, the device comes in the form of goggles that constitute a single unit equipped with a lenses, side shield, top shield, bottom shield made of glass, plastic, and other materials comparable to lead. The lens and shields serve as a physical barrier that protect the wearer from liquid radioactive substances. The goggles come in non-corrective (non-prescription) lens and visual correction.</td>
</tr>
<tr>
<td>Radiation protection goggles</td>
<td>A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. Generally, the device comes in various configurations. Goggles that attenuate photons are made of lead glass, lead, or tungsten. Goggles that attenuate neutrons are made of hydrogenic materials.</td>
</tr>
<tr>
<td>Patient radiation protection spectacles</td>
<td>A personal protection device that covers the patient’s eyes and protects them from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. The protective glasses come in various configurations. Goggles that attenuate photons are made of lead glass, lead, or tungsten. Goggles that attenuate neutrons are made of hydrogenic materials.</td>
</tr>
<tr>
<td>Radiation face protector</td>
<td>A transparent or opaque personal protection device that protects the face and eyes of medical personnel and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. The device is generally made of materials comparable to lead. The glasses generally consist of a frame with lenses and side shields made of materials comparable to lead such as glass and plastic. The lenses and the shield also serve as physical barrier that protects from liquid radioactive substances.</td>
</tr>
<tr>
<td>Operator radiation protection spectacles</td>
<td>A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. The device is generally made of materials comparable to lead. The glasses generally consist of a frame with lenses and side shields made of materials comparable to lead such as glass and plastic. The lenses and the shield also serve as physical barrier that protects from liquid radioactive substances.</td>
</tr>
<tr>
<td>Gonadal radiation protector</td>
<td>A personal protection device that attenuates unnecessary radiation exposure in diagnostic, medical, or dental procedures, and shields the gonad of the patient and the operator. The device comes in various types – e.g. 1). In an anatomical design indicated for the gonad: 2). Directly worn on the body: 3). Installed on the wall or in the radiation emitting device with multi-joint arm. The protectors for the male gonad and female gonad are usually made of lead or other materials comparable to lead.</td>
</tr>
<tr>
<td>Radiation protection blanket</td>
<td>A personal protection device that protects specific body parts of the patient, operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment. Generally, the blanket used for diagnostic X-ray and nuclear medicine consists of a liquid resistant outer cover that covers a thin sheet made of lead or other materials comparable to lead. The blanket for neutron attenuation is made of.</td>
</tr>
<tr>
<td>Radiation protection collar</td>
<td>A personal protection device that protects the neck or thyroid of the patient, the operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment. Some can be used alone or some are designed as an accessory.</td>
</tr>
<tr>
<td>Thyroid gland radiation protector</td>
<td>A radiation protection device specifically designed to shield the thyroid of the patient and the operator etc. from unnecessary radiation exposure from diagnostic drugs or dental procedure. The device forms an attenuation barrier between thyroid and primary radiation source or scattered radiation source. In order to shield the thyroid region of the throat, a structural thyroid protector is also available which is to be installed on the wall.</td>
</tr>
<tr>
<td>Stationary radiation protection barrier</td>
<td>A device for permanent installation that forms a structural barrier that shields or attenuates radiation emitted from primary radiation source or scattered radiation source. Usually, the device is equipped with a solid or transparent barrier that protects the patients from unnecessary exposure to radiation emitted from diagnostic or therapeutic radiation emitting devices. The device is also used to protect patients during diagnosis or.</td>
</tr>
<tr>
<td>Radiation protection cap</td>
<td>A personal protection device that protects the head of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical procedures for diagnosis and treatment. The device forms a physical radiation attenuation barrier between the person and the primary radiation source or scattered radiation source. Most of them have an insertion slit made of transparent lead glass or plastic that allows visual inspection inside. Different materials.</td>
</tr>
<tr>
<td>Mobile radiation protection barrier</td>
<td>A stand-alone, movable barrier that protects the operator etc. from unnecessary exposure to radiation used for medical diagnosis, treatment and dental procedures. The device forms a physical radiation attenuation barrier between the person and the primary radiation source or scattered radiation source. Most of them have an insertion slit made of transparent lead glass or plastic that allows visual inspection inside. Different materials.</td>
</tr>
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<td>Description</td>
<td>Details</td>
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</tr>
<tr>
<td>Radiation protection curtain</td>
<td>A flexible radiation protection tool that protects the operator etc. from unnecessary exposure to radiation emitted from the patient and the radiation used for medical or dental procedures. The tool is a flexible radiation shield/attenuation barrier installed between the person and primary radiation source or scattered radiation source. It is designed to be hung from a rod or track attached to the ceiling, wall, or the radiation source.</td>
</tr>
<tr>
<td>Chest X-ray photofluorographic protective box</td>
<td>A protective box that surrounds the X-ray source, the mirror camera entry face, and the patient positioned between them so as to protect the operator from radiation scattered from the patient and leaked from the X-ray source during a chest X-ray.</td>
</tr>
<tr>
<td>Compact thermoluminescent dosimetry electrometer</td>
<td>A stand-alone, external detection unit that reads the radiation absorbed by a thermoluminescence dosimeter (TLD) brick. TLD brick is used to measure the radiation dose emitted to the phantom, eyes and other organs with high radiosensitivity. The unit usually consists of single or multiple units such as a detector, electrometer, or calibrator.</td>
</tr>
<tr>
<td>Mercury capillary thermometer</td>
<td>A measuring device that measures the body temperature of the patient. The device is a thin hollow glass tube with both ends sealed. The bulb at the bottom is filled with mercury. The device functions based on the capillary principle. The medium filled in the bulb expands in proportion to the recorded temperature.</td>
</tr>
<tr>
<td>Alcohol capillary thermometer</td>
<td>A measuring device that measures the body temperature of the patient. The device is a thin hollow glass tube with both ends sealed. The bulb at the bottom is filled with colored alcohol. The device functions based on the capillary principle. The medium filled in the notched column expands in proportion to the recorded temperature.</td>
</tr>
<tr>
<td>Colour-indicating thermometer</td>
<td>A measuring device that measures the body temperature of the patient. The device is sealed in the tip of a plastic or metal strip, and indicates the body temperature by using an array of thermochemical cells (dots) that change in color tone according to the recorded body temperature.</td>
</tr>
<tr>
<td>Reusable thermometer probe</td>
<td>A device is connected to a clinical thermometer, and usually inserted into a body orifice or placed on the body surface to measure the body temperature. The device is indicated for temporary use, and short-term use in the oral cavity up to the pharynx, ear canal up to the tympanic membrane or nasal cavity only. It is reusable after cleaning.</td>
</tr>
<tr>
<td>Thermometer sensor conversion adapter</td>
<td>An adaptor that converts thermocouple input signals into thermistor thermometer input signals.</td>
</tr>
<tr>
<td>Aneroid sphygmomanometer</td>
<td>A device that consists of a pressurizable cuff that is wrapped around the arm, a pneumatic pressure adjuster valve for the cuff, and an aneroid manometer.</td>
</tr>
<tr>
<td>Mercury sphygmomanometer</td>
<td>A device that measures the arterial blood pressure indirectly (non-invasively). It consists of an expandable cuff to be wrapped around the arm, and a valve that regulates pressure in cuff and manometer.</td>
</tr>
<tr>
<td>Single-use intravenous line manometer</td>
<td>A sterilized plastic pressure stick connected to an infusion line to measure venous blood pressure using the water manometer method. This device is for single-use.</td>
</tr>
<tr>
<td>Mechanical stethoscope</td>
<td>A mechanical hearing device used to hear the sound of heart and lungs. Usually, the listening head has a membrane which is connected to the head gear equipped with ear olives (to be inserted in the user's ear) by a Y-shaped branch tube. Usually, the following.</td>
</tr>
<tr>
<td>Fetal stethoscope</td>
<td>A mechanical hearing device used to listen to the fetal heartbeat. Usually, it is a hollow tube (trumpet shape), and transmits the fetal heartbeat via an inner channel by aerial conduction.</td>
</tr>
<tr>
<td>Esophageal stethoscope</td>
<td>A type of mechanical stethoscope designed to be inserted into the patient's esophagus to listen to the sound of the heart and lungs.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
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</tr>
<tr>
<td>Percussion hammer</td>
<td>A metal (usually, stainless steel) or wooden device that consists of a handle, a shaft, and a head. Used to transmit a force to the body in order to test a reflex. The handle is designed to fit in the palm, usually round, and tapered to the top. The head is placed at the top of.</td>
</tr>
<tr>
<td>Powered percussion hammer</td>
<td>A spring type percussion hammer with a lock and release spring stopper at the piston head. Used to transmit a measured force to the body in order to test a reflex.</td>
</tr>
<tr>
<td>Ploss switching valve</td>
<td>A three way switching valve installed between the stethoscope applied over the heart, the blood pressure measurement cuff, and ear piece. It eliminates other sounds to focus on one sound (heartbeat or blood pressure).</td>
</tr>
<tr>
<td>Powered chest percussor</td>
<td>An electric device used to transmit vibrations to the patient's thoracic wall in order to assist elimination of retained mucosa from the lungs and improve fluid discharge from bronchus. It is operated by electricity or compressed gas.</td>
</tr>
<tr>
<td>Intrauterine pressure transducer</td>
<td>A transducer used to measure the pressure in the uterine cavity.</td>
</tr>
<tr>
<td>Sphygmograph</td>
<td>A graphic printer of arterial pulse waveforms. Usually, it is equipped with a lever. The shorter end of the lever is placed on the radial artery on the wrist, and the longer end is equipped with a stylet that records the changing pulses (usually on a moving sheet).</td>
</tr>
<tr>
<td>Pulse wave meter</td>
<td>The device adopts such means as pressure, photoelectricity, strain gauge, and impedance, and displays the waveforms of wave motions that represent the changes of pressure in the blood vessels conveyed toward the periphery when cardiac contraction pushes the blood.</td>
</tr>
<tr>
<td>Gas flow transducer</td>
<td>A conductor that converts gas flow rate into electric signals, and sends the signals to a measurement/display device.</td>
</tr>
<tr>
<td>Single-use pulse oximeter probe</td>
<td>A device that is used on the fingers, ear lobes, bridge of the nose, feet, or other parts of pediatric and adult patients, irradiates light via skin, and detects the amount of light absorbed by oxyhemoglobin and deoxyhemoglobin in arterial tissue blood. The base unit receives the signals, and indicates the result. This device is for single-use.</td>
</tr>
<tr>
<td>Single-use thermometer probe</td>
<td>A device is connected to a clinical thermometer, and usually inserted into a body orifice or placed on the body surface to measure the body temperature. The device is intended for temporary use, and short-term use in the oral cavity up to the pharynx, ear canal up to the tympanic membrane or nasal cavity only. This device is for single-use.</td>
</tr>
<tr>
<td>Reusable pulse oximeter probe</td>
<td>A device that is used on the fingers, ear lobes, bridge of the nose, feet, or other parts of pediatric and adult patients, irradiates light via skin, and detects the amount of light absorbed by oxyhemoglobin and deoxyhemoglobin in arterial tissue blood. The base unit receives the signals, and indicates the result. This device is for single-use.</td>
</tr>
<tr>
<td>Tremor transducer</td>
<td>A device that measures the degree of tremor caused by some diseases.</td>
</tr>
<tr>
<td>Reusable electrocardiograph electrode</td>
<td>A conductor to be placed on the body surface (usually, strapped by a belt using contact gel). It transmits electric signals detected on the body surface to a processing device (cardiac electrical activity is represented as a graph). A general device that records this cardiac electrical activity is called an electrocardiograph (ECG). This device is for single-use.</td>
</tr>
<tr>
<td>Single-use electrocardiograph electrode</td>
<td>A conductor to be placed on the body surface. It transmits electric signals detected on the body surface to a processing device (cardiac electrical activity is represented as a graph). A general device that records this electrical activity is called an electrocardiograph (ECG). This device is for single-use.</td>
</tr>
<tr>
<td>Electrocardiograph cable or lead</td>
<td>A device that transmits a patient's electrocardiogram signals to an electrocardiograph (ECG). The device is placed on the chest using electrodes according to a specific pattern.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
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</tr>
<tr>
<td>Radiolucent electrocardiograph cable/lead</td>
<td>A device that transmits a patient’s electrocardiogram signals to an electrocardiograph (ECG). The device is placed on the chest using electrodes according to a specific pattern. Some are specifically designed so as to project subtle X-ray images for instance for 36038000 1 1 N/A N/A</td>
</tr>
<tr>
<td>Intracardiac electrocardiograph cable or switch</td>
<td>Cables or switches are externally connected to a guide wire and catheter inserted into the central vein, and transmit cardiac electric signals from the patient to an external monitor (e.g., electrocardiograph). Some transmit a stimulating electric current to the heart temporarily for examination mainly. 35562020 1 1 N/A –</td>
</tr>
<tr>
<td>Neonatal electrocardiograph electrode</td>
<td>A conductor for neonates to be placed on the body surface, and transmit electric signals detected on the body surface to a processing device (cardiac electrical activity is represented in a graph). A general device that records this electrical activity is called an electroencephalograph (EEG). 17460000 1 1 applicable –</td>
</tr>
<tr>
<td>Apex cardiograph transducer</td>
<td>A device that detects cardiac motions (e.g., acceleration, speed, and displacement) according to the change in mechanical or electrical characteristics. The results are displayed on the base unit. 33314000 1 12 applicable applicable</td>
</tr>
<tr>
<td>Self-suction ECG electrode system</td>
<td>An automatic vacuum type electrode device that is used to attach electrodes to subjects in an electrocardiogram examination. 70065000 1 12 applicable applicable</td>
</tr>
<tr>
<td>Electroencephalograph electrode</td>
<td>A conductor that records the changes in electric potential in various cerebral regions from the scalp. A general device that records this electrical activity is called an electroencephalograph (EEG). 11440001 1 1 applicable –</td>
</tr>
<tr>
<td>Electroencephalographic electrode head cap</td>
<td>A special type of patient cap used for electroencephalogram (EEG) recording. Electrodes suitable for measuring electroencephalogram potential are installed around the inner surface of the cap. The cap eliminates the process of pasting individual electrodes to the patient’s scalp. 17554000 1 1 applicable –</td>
</tr>
<tr>
<td>Electromyograph body surface electrode</td>
<td>A conductor that detects biological electric signals in muscles and neural tissues on the body surface. A general device that records the electrical activity detected by the conductor is an electromyograph (EMG). 11441001 1 1 applicable –</td>
</tr>
<tr>
<td>Reusable body surface electric stimulator electrode</td>
<td>An electrodes placed on the body surface, and used along with an electrostimulator to transmit electricity to tissues. Both cathodes and anodes are necessary. The electrodes are reusable after proper cleaning. 43441000 1 1 applicable –</td>
</tr>
<tr>
<td>Body surface electric stimulator electrode</td>
<td>A conductor placed on body surface, and used to transmit electricity to tissues. Both cathodes and anodes are necessary. 34374001 1 1 applicable –</td>
</tr>
<tr>
<td>Body surface stimulator probe</td>
<td>Probes for the body surface specifically designed for use in combination with a stimulator. 36957001 1 1 applicable –</td>
</tr>
<tr>
<td>Electronystagmograph electrode</td>
<td>Conductors that are placed above and below the eye sockets, and transmit electric signal for the evaluation of rapid eye movement (ocular nystagmus). A general device that records this electrical activity is called an electronystagmograph (ENG). 11442000 1 1 applicable –</td>
</tr>
<tr>
<td>Device Type</td>
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</tr>
<tr>
<td>Nasopharyngeal electrode</td>
<td>A conductor that is temporarily placed on the nasopharynx for recording electrical activity.</td>
</tr>
<tr>
<td>Electroretinograph electrode</td>
<td>A conductor that is placed near the eyes and transmits electric signals for retinal evaluation. A general device that records this electrical activity is called an electroretinograph (ERG).</td>
</tr>
<tr>
<td>Sweat test electrode</td>
<td>A conductor that is placed on the skin of the arm or leg, and measures sodium and chlorine concentration in sweat to diagnose cystic fibrosis.</td>
</tr>
<tr>
<td>Electrooculograph electrode</td>
<td>A conductor attached near the eye to transmit signals to diagnose and evaluate extraocular neuromuscular system.</td>
</tr>
<tr>
<td>Fetal scalp surface electrode</td>
<td>A conductor that is attached to the scalp of fetus in utero, and transmits electric signals to allow fetal vital signs to be monitored.</td>
</tr>
<tr>
<td>Fetal scalp clip electrode</td>
<td>An electrical conductor designed to establish an electrical connection between fetal skin and an external monitoring device by pinching the skin using a single-use clip.</td>
</tr>
<tr>
<td>Visual evoked response electrode</td>
<td>A conductor that transmits changes in electric potential from the skin surface in order to measure visual evoked response.</td>
</tr>
<tr>
<td>Respiration sensor</td>
<td>A sensor used to detect nasal and oral flow and pressure. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).</td>
</tr>
<tr>
<td>Thoracic and abdominal respiration sensor</td>
<td>A sensor used to detect chest and abdominal activity. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).</td>
</tr>
<tr>
<td>Body motion sensor</td>
<td>A sensor used to detect body movement. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).</td>
</tr>
<tr>
<td>Sleep assessment sensor</td>
<td>Electrodes and sensors that are connected to a sleep evaluation device, and measures the patient’s bio-physical phenomena. Parameters measured by the sleep evaluation device are electrocardiogram, electroencephalogram, thoracic wall movement, nasal and oral cavity airflow, eye movement, oxygen saturation, and electromyogram according to which.</td>
</tr>
<tr>
<td>Toco transducer</td>
<td>A device that converts uterine contractions into electric signals during delivery, and is used with a fetal heart monitor (the results are displayed). Obstetrics is the field of medicine that covers obstetrical technique and midwifery (the medical field that deals with childbirth).</td>
</tr>
<tr>
<td>Reusable urine flowmeter</td>
<td>A device that directly or indirectly measures urinary flow rate and urine volume during normal urination or urethral catheterization. Measurement is mechanical, electrical or a combination of both. This is reusable use.</td>
</tr>
<tr>
<td>Urine flow transducer</td>
<td>A device that measures the patient’s urine volume by time unit. The measurement unit is liter/minute.</td>
</tr>
<tr>
<td>Petechiometer</td>
<td>Usually, it refers to a device that causes petechia (bleeding) of diameter &lt; 3 mm on the skin surface. The depth of this bleeding can be measures for evaluation of fragility of a capillary blood vessel. Other methods of measurement are preferred in some cases.</td>
</tr>
<tr>
<td>Rotary spirometer</td>
<td>A mechanical device that measures pulmonary capacity based on exhaled air blown into a rotating drum.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
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</tr>
<tr>
<td>Manually-operated diagnostic spirometer</td>
<td>A mechanical device that measures pulmonary air volume and air flow for diagnosis or examination of pulmonary diseases. These measurement values provide information on the patient's pulmonary functions, enabling comparison with normal values or previous.</td>
</tr>
<tr>
<td>Exhalation gas detector</td>
<td>A device that detects the carbon dioxide level in the air exhaled by the patient. A test paper to be used for detection contains a chemical substance whose color changes with the carbon dioxide level in the exhaled gas. The unit includes a color chart for judgement.</td>
</tr>
<tr>
<td>SAS screener</td>
<td>A device that monitors presence/absence of the air flow from the nose and oral cavity when the patient is asleep. Some are made for single-use.</td>
</tr>
<tr>
<td>Direct ophthalmoscope</td>
<td>A hand-held ophthalmoscope (power source or battery-operated) used for intraocular examination. It consists of a light, a mirror with a hole (the examiner looks through this hole), and a dial to select lenses with different degrees. Some provide a normal image.</td>
</tr>
<tr>
<td>Monocular indirect ophthalmoscope</td>
<td>An ophthalmoscope used for intraocular examination. It consists of a light source and a hand-held lens. Some provide an inverted image magnified approximately 2-5 times.</td>
</tr>
<tr>
<td>Pleoptophor</td>
<td>An ophthalmic device used for training for foveal fixation. It is also used to treat eccentric fixation (strabismus) by dazzling the vicinity of the macula lutea, and relatively enhancing the visual capability of the central fovea of retina.</td>
</tr>
<tr>
<td>Binocular indirect ophthalmoscope</td>
<td>An ophthalmoscope used for intraocular examination. It provides a stereoscopic image for examination. It is held by hand, fixed by a head belt, or installed on a special spectacles frame.</td>
</tr>
<tr>
<td>Euthyscope</td>
<td>A device used to examine and correct the fundus oculi. The improved funduscope (a mirror with a hole used for intraocular examination) projects bright light that traces a 30° arc of the fundus oculi. The center of this light flux is blocked by a black disc that covers the fovea centralis (a depression in the center of the yellow spot of the retina where only cones are seen, and there are no blood vessels). It is also used to treat amblyopia (a state where one or more eyes fails to achieve normal visual acuity even if it does not have any specific disease).</td>
</tr>
<tr>
<td>Visual field plotter</td>
<td>An ophthalmic device used to measure and record the visual field and the sensitivity of a fixed eye. Used for examination of the photosensitivity, color sensitivity, and the ability to detect/identify an object and pattern.</td>
</tr>
<tr>
<td>Automatic perimeter</td>
<td>A device that measures the visual field by recording the patient's response to small light spots (dots) automatically displayed at various positions. Some print out the measured visual field.</td>
</tr>
<tr>
<td>Manually-operated perimeter</td>
<td>A device that measures the visual field by recording the patient's response to small light spots (dots) manually displayed at various positions. Some record the visual field curve on a pre-printed card (chart).</td>
</tr>
<tr>
<td>Campimeter</td>
<td>A device used to measure the central visual field. A hand-held device that displays a white spot is moved from the periphery to the center of a black background (tangent screen). The patient stares at the center from a distance of approximately 2 meters, and tells when the target is seen. This is Tangent Screen Testing, a simple measurement of the visual field. Some use a dedicated tool that projects bright light spots (known as a campimeter) or a simple black stick with a white dot on one end as the target.</td>
</tr>
<tr>
<td>Scotometer</td>
<td>A device that measures the site of deteriorated sensitivity in the visual field (relative scotoma), absolute scotoma and blind spot.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
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</tr>
<tr>
<td>Retinoscope</td>
<td>An ophthalmic device used for examination, diagnosis and evaluation of refractive error by projecting a beam, and observing the movement of the region of the retinal surface illuminated and the reflection of the released beam.</td>
</tr>
<tr>
<td>Keratoscope</td>
<td>An ophthalmic diagnostic device used for cornea examination. Some have a circular plate with white and black concentric circles printed on it (Placido disk). Where there is astigmatism, the rings look distorted.</td>
</tr>
<tr>
<td>Corneal topography system</td>
<td>A system used to measure the curvature of the anterior corneal surface at an ophthalmology department. Some include a videokeratoscope and a computer equipped with an image processing function. Some are equipped with patient data management.</td>
</tr>
<tr>
<td>Corneal topography system with pupillometer function</td>
<td>A system used to measure the curvature of the anterior corneal surface at an ophthalmology department. Some include a videokeratoscope and a computer equipped with an image processing function. Some are equipped with patient data management.</td>
</tr>
<tr>
<td>Refractometer</td>
<td>A device that measures the degree of ocular refractive error. Recent devices automatically measure the degree and print out the result.</td>
</tr>
<tr>
<td>Refractometer with subjective refraction measurement function</td>
<td>A refractometer that examines subjective refraction.</td>
</tr>
<tr>
<td>Refractometer with subjective refraction measurement function</td>
<td>A refractometer that can measure the radius of the cornea curvature, or has a corneal topography function.</td>
</tr>
<tr>
<td>Refractometer with subjective refraction measurement function</td>
<td>A refractometer that examines subjective refraction, and can measure the radius of the cornea curvature, or has a corneal topography function.</td>
</tr>
<tr>
<td>Refractometer with axial length measurement function</td>
<td>A refractometer that can measure the eye axial length and the radius of the cornea curvature, or has a corneal topography function.</td>
</tr>
<tr>
<td>Rotary prism</td>
<td>Prisms with various powers used to evaluate the ocular muscle in a visual function test.</td>
</tr>
<tr>
<td>Refractor</td>
<td>A device installed lenses with various powers in order to measure ocular refraction. A set of trial lenses that function mechanically.</td>
</tr>
<tr>
<td>Binocular vision test unit</td>
<td>An ophthalmic device used to examine visual function. A patient wears red/green glasses, looks at 4 light spots (one each of white and red spot and two green spots), and answers how they look. From the result, inhibition is assessed.</td>
</tr>
<tr>
<td>Retinometer</td>
<td>A hand-held diagnostic device (power source or battery-operated) used to examine potential acuity. It is used, for example, in a visual acuity test for patients with an opacified lens.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
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</tr>
<tr>
<td>Adaptometer</td>
<td>A device that measures the time required for retinal adaptation and minimum light threshold by varying the intensity of a stimulus light source.</td>
</tr>
<tr>
<td>Ophthalmotropometer</td>
<td>An ophthalmic device used to measure eye movement.</td>
</tr>
<tr>
<td>Optometer</td>
<td>An ophthalmic device used to measure the near point distance.</td>
</tr>
<tr>
<td>Optomyometer</td>
<td>An ophthalmic device used to measure the relative strength of the ocular muscle.</td>
</tr>
<tr>
<td>Pupillograph</td>
<td>A device used to record the pupil's response to reflected light.</td>
</tr>
<tr>
<td>Diplopiometer</td>
<td>An ophthalmic device used for the diagnosis of diplopia (visual symptom where two images of a single object are perceived in the visual cortex).</td>
</tr>
<tr>
<td>Anomaloscope</td>
<td>A device used to detect color vision defects by allowing the patient to mix the spectrum of colors and obtain the same color as the presented sample.</td>
</tr>
<tr>
<td>Phorometer</td>
<td>An ophthalmic device used to test ocular balance.</td>
</tr>
<tr>
<td>Haploscope</td>
<td>A device used to assess binocular visual function and for examination, treatment and training for amblyopia and strabismus. It consists of 2 movable observation tubes. Each tube has a slide carrier, a weak light source to illuminate the slide and a strong light source to produce a residual image. Some are used to measure the strabismus (imbalance in the strength of extraocular muscles), and assess binocular vision (seeing with both eyes), or treat inhibition and amblyopia (unclear vision with no apparent disease).</td>
</tr>
<tr>
<td>Nystagmus inducing tape</td>
<td>An ophthalmic device with a long, narrow belt made of flexible material such as cloth, with a series of pattern printed on it. The belt crosses the patient's visual field so as to induce optokinetic nystagmus (abnormal and irregular eye movement), and examine loss of sight.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
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</tr>
<tr>
<td><strong>Distometer</strong></td>
<td>A device used to measure the distance between the cornea and lens for vision correction. It is also used to facilitate measurement of the lens position and change of image for refraction.</td>
</tr>
<tr>
<td><strong>Synoptophor</strong></td>
<td>An ophthalmic device used for assessment and training of the binocular visual function (capacity to focus on one object with both eyes). Usually, it is used for diagnosis of strabismus (ocular deviation that cannot be controlled by the patients themselves). There are different forms of strabismus such as stereopsis (stereoscopic vision), amblyopia (one eye failing to achieve normal visual acuity), and exotropia/esotropia (strabismus/squint).</td>
</tr>
<tr>
<td><strong>Central critical flicker fusion frequency meter</strong></td>
<td>A device that measures the central flicker value.</td>
</tr>
<tr>
<td><strong>Contrast sensitivity meter</strong></td>
<td>A device that measures contrast sensitivity.</td>
</tr>
<tr>
<td><strong>Pupillography device with optometric function</strong></td>
<td>A device with multiple functions: i.e., a near point ruler, and a function for recording the response of the pupil to reflected light or a visual target.</td>
</tr>
<tr>
<td><strong>Ophthalmoscopic diagnostic set</strong></td>
<td>A set consisting of combination of ophthalmoscopic diagnostic devices that are categorized into different types. A mirror body of the direct ophthalmoscope is detachable from the handle. By utilizing this structure, this set is intended to be used in a way that the mirror bodies of the direct ophthalmoscope and an otoscope speculum are interchangeably attached to the handle.</td>
</tr>
<tr>
<td><strong>Equilibrium function test equipment</strong></td>
<td>A device that indicates the position and movement of the center of gravity of a human body standing upright on a scale, and performs quantitative analysis.</td>
</tr>
<tr>
<td><strong>Tuning fork</strong></td>
<td>A U-shaped device usually made of stainless steel with a handle at the bottom of the U-shape. The vertical part at the top of &quot;U&quot; is cut to a length that makes a sound having a specific wavelength when hit by a hard object (usually, rubber). Used for audiometry.</td>
</tr>
<tr>
<td><strong>Gait physiologic analyser</strong></td>
<td>A device used to test the gait and gait pattern. It utilizes a platform that measures the reaction force from the ground, takes an image, assesses the motion of the knees, ankles and hip joints, and measures the force and torque. It is used to support diagnosis and planning of corrective measures for the gait and gait-related problems.</td>
</tr>
<tr>
<td><strong>Hand dynamometer</strong></td>
<td>A device that measures, examines, and coordinates the strength of the muscles of the hands and forearms of the patient. Usually it is used for rehabilitation after stroke.</td>
</tr>
<tr>
<td><strong>Manually-operated cutaneous pain gauge</strong></td>
<td>A manually-operated device used to measure the sensitivity to pain (e.g., puncture with a pin). Also known as an algometer.</td>
</tr>
<tr>
<td><strong>Tropometer</strong></td>
<td>A device that measures the amount of rotation of the axis of the eyeball or a long bone.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
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</tr>
<tr>
<td>Joint movement tester</td>
<td>A tester is used to assess the characteristics of joints. Usually, the assessment is performed before and after surgery of an abnormal joint (e.g., arthroplasty, arthroscopic procedure). It assesses the range of joint movement and normal function.</td>
</tr>
<tr>
<td>Bone-angle scaler</td>
<td>A device used to measure the angle of bones for X-ray examination or surgery. Usually, it is known as a protractor.</td>
</tr>
<tr>
<td>Back dynamometer</td>
<td>A device/instrument used to measure the strength (muscle strength generated when bending the back muscle, in particular). Usually, it is used to control the muscle strength for rehabilitation.</td>
</tr>
<tr>
<td>Slit lamp microscope</td>
<td>A slit-lamp biomicroscope used for observation, examination and photography of the eyeball. It is also used for measurement of intraocular pressure, corneal thickness, and anterior chamber depth. A slit light is projected on the eyeball from an oblique direction, and the movable microscope is aligned to the light in order to observe and measure the reflected surface.</td>
</tr>
<tr>
<td>Ophthalmic light microscope</td>
<td>An optical microscope used for examination, observation, and photography of the eyeball. Some are designed to examine the anterior part of the eye (cornea, aqueous humor, lens, anterior chamber, vitreous body) with a stereoscope. Others are used for fitting contact lenses, follow-up and detection of corneal damage, foreign objects, and diseases. It is usually used with a light source specifically designed for the system known as a slit lamp.</td>
</tr>
<tr>
<td>Colposcope</td>
<td>A special microscope used for examination of the female genital organs (e.g., vagina, cervix).</td>
</tr>
<tr>
<td>Urethrometer</td>
<td>A device specifically designed to be inserted into the urethra, dilate it, and measure the degree of dilation. Usually, the measurement is indicated on the dial.</td>
</tr>
<tr>
<td>Vaginometer</td>
<td>A device that measures the length and diameter of the vagina.</td>
</tr>
<tr>
<td>Endoscopic video image processor</td>
<td>A unit designed to receive electronic signals transmitted from a video endoscope or endoscopic video camera for processing. Some are equipped with a function to correct/enhance the color and light quality, or a function to generate stereoscopic images. The image is reproduced by a visual display unit (VDU), recorded by a video recorder, and stored on computerized media. Some provide hard copy images using another device.</td>
</tr>
<tr>
<td>Endoscope light source/processing unit</td>
<td>A device relying on an external power source which is designed to be used in conjunction with an endoscope (mainly video endoscope) and functions as the light source and processing unit. The device serves as the light source for observation of the surgical field.</td>
</tr>
<tr>
<td>Line-powered endoscope light source</td>
<td>An external powered, dedicated device that provides light for observation of the surgical field and body cavity when using a rigid or flexible endoscope (e.g., laparoscope, gastroscope) and its accessories. It illuminates the site being observed/treated via an optical fiber light source cable connected to the endoscope, while minimizing the heating.</td>
</tr>
<tr>
<td>Battery-powered endoscope light source</td>
<td>A battery-powered, dedicated device that provides the light for observation of the surgical field and body cavity when using a rigid or flexible endoscope (e.g., laparoscope, gastroscope) and its accessories. It illuminates the site being observed/treated via an optical fiber light source cable connected to the endoscope, while minimizing the heating.</td>
</tr>
<tr>
<td>Endoscopic video camera</td>
<td>A camera specifically designed to be used with an endoscope. Some are equipped with voice function. In order to convert optical images into electronic video images, it is connected to a flexible or rigid endoscope directly or via an adaptor.</td>
</tr>
<tr>
<td>Item Name</td>
<td>Description</td>
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</tr>
<tr>
<td>Endoscope peripheral equipment controller</td>
<td>An item connected to an endoscope or other devices to be used in combination with the endoscope, and performs a centralized switching for the devices connected to it.</td>
</tr>
<tr>
<td>Endoscopic balloon pump</td>
<td>A balloon pump that inflates and deflates the balloon attached to an endoscope or an overtube. It assists the insertion of the endoscope.</td>
</tr>
<tr>
<td>Endoscope water supply tank</td>
<td>A water storage tank to be connected to the water supply unit of an endoscope, and supply water.</td>
</tr>
<tr>
<td>Ultrasonic probe driving unit</td>
<td>An externally installed unit that mechanically drives or holds/moves an ultrasonic transducer, and controls the direction of ultrasonic beams. It may be connected to an ultrasonic endoscope that does not have a driving source or an ultrasonic probe. It may include the motor that generates the driving power, motor control circuit, and ultrasonic transducer.</td>
</tr>
<tr>
<td>Flexible bronchoscope curette</td>
<td>A device used with a specific endoscope to collect bronchial samples for histological/pathological diagnosis during a bronchoscopic examination. It is a type of biopsy forceps that has a flexible insertion part such as a metal coil or a plastic tube.</td>
</tr>
<tr>
<td>Cystoscopic rongeur</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It has sturdy blades and powerful force for scraping and cutting hard tissue during endoscopic treatment.</td>
</tr>
<tr>
<td>Rigid bronchoscope curette</td>
<td>A device used with a specific rigid endoscope. It is used to collect bronchial samples for histological/pathological diagnosis during a bronchoscopic examination. Usually, it is a type of metal biopsy forceps. To exactly perform the biopsy, it is equipped with a sharp curette like a nail. It is a rigid device.</td>
</tr>
<tr>
<td>Laparoscopic rigid biopsy forceps</td>
<td>An endoscopic device to be used with a dedicated rigid laparoscope. It is used to collect samples during laparoscopic examination. Usually, the insertion part is made of a metal tube, and inserted into an endoscope.</td>
</tr>
<tr>
<td>Endoscopic scissor forceps</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is used to sever tissue or suture threads. Usually, it consists of a flexible metal coil or plastic tube. It has scissors at the end, and is operated by handles at the other end. It is inserted into a body cavity via the working channel of the endoscope.</td>
</tr>
<tr>
<td>Endoscopic flexible grasping forceps</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is used to hold tissue or foreign matter. Usually, the insertion part is made of a flexible metal coil or plastic tube.</td>
</tr>
<tr>
<td>Endoscopic rigid biopsy forceps</td>
<td>An endoscopic forceps used with a dedicated endoscope. Used to collect samples for histological/pathological diagnosis during endoscopic examination. Usually, the forceps are made of rigid metal tubes. They have a pair of cups at one end, and are operated by</td>
</tr>
<tr>
<td>Endoscopic sponge grasping forceps</td>
<td>A device used with a dedicated endoscope for endoscopic treatment and used for transferring folded gauze or an absorbent cotton pad to the site being treated.</td>
</tr>
<tr>
<td>Laparoscopic spatula</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is used for blunt dissection of tissue adhesions embedded in a wide area. It is used for laparoscopic treatment.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
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<tr>
<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Endoscopic flexible biopsy forceps</td>
<td>An endoscopic forceps used with a dedicated endoscope. Used to collect samples for histological/pathological diagnosis during endoscopic examination. Usually, the forceps are made of rigid metal tubes. They have a pair of cups at one end, and are operated by handles at the other end. They are inserted into a body cavity via an artificial orifice or natural opening.</td>
</tr>
<tr>
<td>Reusable endoscopic cytology brush</td>
<td>A brush used to collect mucosal cells for pathological diagnosis during endoscopic examination. It has a flexible insertion part made of a metal coil or plastic tube, and has a plastic brush at the end to collect mucosa for bronchoscopic examination. This device is reusable.</td>
</tr>
<tr>
<td>Single-use endoscopic cytology brush</td>
<td>A brush used to collect mucosal cells for pathological diagnosis during endoscopic examination. It has a flexible insertion part made of a metal coil or plastic tube, and has a plastic brush at the end to collect mucosa for bronchoscopic examination. This device is reusable.</td>
</tr>
<tr>
<td>Endoscopic periosteal elevator and raspatory</td>
<td>Used with an endoscope for endoscopic treatment. It has a swab (folded gauze or absorbent cotton pad) at the end of the shaft.</td>
</tr>
<tr>
<td>Endoscopic non-active knife</td>
<td>A non-active knife used for dissecting the urinary tract via the forceps outlet of the endoscope.</td>
</tr>
<tr>
<td>Bronchoscopic aspiration tube</td>
<td>A device used with a dedicated endoscope for endoscopic treatment and used to aspirate waste matter from the respiratory tract and bronchus. Made of a plastic tube.</td>
</tr>
<tr>
<td>Reusable endoscopic sclerotherapy injection needle</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is used to inject drugs into the mucosa or a blood vessel for sclerotherapy. It has an injection needle at the end of the flexible tube and a connector of the syringe at the other end. This device is reusable.</td>
</tr>
<tr>
<td>Reusable rigid endotherapy lithectomy forceps</td>
<td>A device used with a dedicated endoscope. It is intended to be used to grasp and remove stones during endotherapy. It consists of a thin shaft and a wire basket at the distal end in which the stones are caught (picked up) for extraction. This device is reusable.</td>
</tr>
<tr>
<td>Resectoscope suction apparatus</td>
<td>A device used with an endoscope and its direct application to assist the use of the endoscope. The dedicated glass bottle is equipped with a rubber ball that is manually operated. Connected to a resectoscope and used to wash off residual tissue and coagulated matter using the cleaning solution during surgery.</td>
</tr>
<tr>
<td>Reusable endoscopic cannula</td>
<td>A cannula used to convey a drug solution or contrast medium into the body cavity for diagnosis and treatment during endoscopic examination. This device is reusable.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>Single-use natural orifices endoscopic cannula</td>
<td>A cannula used to convey a drug solution or contrast medium into a body cavity via a natural orifice of human body for diagnosis or treatment during endoscopic examination. This device is for single-use.</td>
</tr>
<tr>
<td>Reusable endoscopic injection needle</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is used to inject drugs into the mucosa or a blood vessel for hemostasis, sclerosis, or other purposes. It has an injection needle at the end of the flexible tube, and a connector of the syringe at the other end. This device is reusable.</td>
</tr>
<tr>
<td>Endoscope lens cleaner</td>
<td>A device that supplies the air or fluid onto the lens surface in order to eliminate blood and foreign matter. It is made of metal or plastic and has a tubular configuration. It is attached to the insertion part of endoscope. The device that transfers the air or fluid is a manual pump or gravity dependent infusion bag.</td>
</tr>
<tr>
<td>Endoscopic colonoscope stiffener</td>
<td>A special cable that is inserted into a flexible colonoscope in order to adjust the rigidity of the colonoscope in a colonoscopic examination.</td>
</tr>
<tr>
<td>Endoscopic measuring device</td>
<td>A dedicated device used with an endoscope and its direct applications to measure the size of objects in the visual field during an endoscopic examination. It is made of a flexible metal coil or plastic tube, and has a scale at the distal end.</td>
</tr>
<tr>
<td>Arthroscopic surgical probe</td>
<td>A surgical device used for examination, probing, and treatment inside the joint.</td>
</tr>
<tr>
<td>Endoscopic obturator</td>
<td>This device is a component of an endoscope that consists of several parts required to achieve its function. At the distal end, it has a round head or tip which is inserted into a sheath in order to fill the lumen of the sheath (open end) of the rigid endoscope. It makes it easy to insert the sheath into the body and prevents injury to the patient.</td>
</tr>
<tr>
<td>Endoscopic inflation bulb</td>
<td>A device used with an endoscope and its direct applications that assists the use of the endoscope. The rubber ball-like device is used to transfer the air via the endoscope in order to secure the endoscopic visual field.</td>
</tr>
<tr>
<td>Reusable endoscopic dilator</td>
<td>A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. It is made of a flexible or rigid rod or tube. The device is inserted via the skin (subcutaneously) and used, for example, in the urethra and urinary tract. This device is reusable.</td>
</tr>
<tr>
<td>Item Description</td>
<td>Description</td>
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</tr>
<tr>
<td>Single-use natural orifices endoscopic dilator</td>
<td>A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. Dilation is performed from a natural orifice of the human body, in the urethra or urinary tract, for example. It is a flexible or rigid rod or tube. This device is for single-use.</td>
</tr>
<tr>
<td>Ultrasound balloon</td>
<td>A balloon that seals an ultrasonic medium. Used in combination with an ultrasonic endoscope or a probe used for an ultrasound image diagnostic device. This device is for single-use.</td>
</tr>
<tr>
<td>Endoscopic ligation instrument</td>
<td>A device or tool used to close internal wounds by tying the end of suture threads in endoscopic treatment. Known as a thread ligator.</td>
</tr>
<tr>
<td>Endoscopic sheath</td>
<td>This device is a component of an endoscope that consists of several parts required to achieve its function. This device is a thin metal tube, and other parts are inserted into this device, and assembled so as to complete the surgical endoscopic device.</td>
</tr>
<tr>
<td>Reusable non-active endotherapy device</td>
<td>A device used with a dedicated endoscope for endoscopic treatment for mechanical operations such as holding, collecting, resecting, clipping, ligating the tissue or foreign matter, sending drug solutions, suctioning, dilating lumens, and probing. It functions without electricity (e.g., high-frequency waves, electromagnetism, ultrasound, laser energy). This device is reusable.</td>
</tr>
<tr>
<td>Single-use natural orifices non-active endotherapy device</td>
<td>A device used with a dedicated endoscope for endoscopic treatment. It is inserted via a natural orifice of the human body for mechanical operations such as holding, collecting, resecting, clipping, and ligating the tissue or foreign matter, sending drug solutions, suctioning, dilating lumens, and probing, or for illuminating tissue, etc., by light supplied from the light source via the optical fiber bundle, etc. The mechanical operations function without electricity (e.g., high-frequency waves, electromagnetism, ultrasound, laser energy). This device is for single-use.</td>
</tr>
<tr>
<td>Tissue storage pouch</td>
<td>A device that is inserted into the abdominal cavity in endoscopic surgery to prevent the dispersion of separated tissues, and isolate/store the tissues. This device is sterilized and for single-use.</td>
</tr>
<tr>
<td>Reusable tissue storage pouch introducer</td>
<td>A device that assists the insertion of a tissue retrieval sac into a body cavity. This is sterilized before use, and reusable after sterilization or cleaning.</td>
</tr>
<tr>
<td>Resected organ remover</td>
<td>A device used to hold or fix an organ in its original position, or remove it from the body.</td>
</tr>
<tr>
<td>Single-use infection-prevention endoscopic sheath for natural orifices</td>
<td>A cover (sheath) applied to an endoscope to protect the insertion part from direct contact with the mucosa, blood or body fluids. This device is for single-use for a natural orifice.</td>
</tr>
<tr>
<td>Laser/laparoscope adaptor</td>
<td>The adaptor is used to connect the laparoscope to the laser or the laser arm for laparoscopic laser treatment.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
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<tr>
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</tr>
<tr>
<td><strong>Endoscopic laser filter</strong></td>
<td>A component of an endoscope that requires the addition of a filter to the optical device as an eyepiece. Used to protect the operator's eyes from laser energy generated from the optical unit during laser treatment.</td>
</tr>
<tr>
<td><strong>Adaptor for endoscope element</strong></td>
<td>Connectors that enable to complete an endoscopic assembly by connecting or integrating single or multiple endoscopic parts, and the connections to other devices (e.g., laser), as well as parts used to add functions. Some are connected to the stopcock or tool port in order to introduce a device or catheter, or aspirate/introduce fluid.</td>
</tr>
<tr>
<td><strong>Multiport adaptor</strong></td>
<td>An adaptor that has a port for connecting a tracheal tube and respiratory circuit with an insertion port for a bronchoscope or a balloon catheter.</td>
</tr>
<tr>
<td><strong>Natural orifices endoscope defroster</strong></td>
<td>Applied to the surface of an endoscopic lens that is inserted via a natural orifice. Antifogging liquid or solid that prevents dew condensation caused by the difference of the temperature between the endoscope and inner body.</td>
</tr>
<tr>
<td><strong>Endoscope fixation device</strong></td>
<td>A device that holds and adjusts a laparoscope, various types of endoscopes, and other tools for procedures at the desired position during surgery. It consists of joints and rigid or semi-rigid arms. It simply holds an endoscope.</td>
</tr>
<tr>
<td><strong>Gas pressure transducer</strong></td>
<td>A device used to convert gas pressure into an electric signal for subsequent display or processing by the base unit.</td>
</tr>
<tr>
<td><strong>Dental intraoral camera</strong></td>
<td>A device that displays oral cavity information on a monitor for treatment and explanation to the patient.</td>
</tr>
<tr>
<td><strong>Flow clinical chemistry analyser</strong></td>
<td>An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances and human tissue samples. With this device, a chemical reaction occurs in a continuous flow of fluid. Samples are picked up from the sample cup on the turntable at designated intervals and introduced into the flow of reagents. Through the time for mixture, incubation and coloration is secured and then the absorbance of the reaction is measured.</td>
</tr>
<tr>
<td><strong>Mobile flow clinical chemistry analyser</strong></td>
<td>An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances and human tissue samples. With this device, a chemical reaction occurs in a continuous flow of fluid. Samples are picked up from the sample cup on the turntable at designated intervals and introduced into the flow of reagents. Through the time for mixture, incubation and coloration is secured and then the absorbance of the reaction is measured.</td>
</tr>
<tr>
<td><strong>Discrete automated clinical chemistry analyzer</strong></td>
<td>A device that certainly enables to automate or mechanize manual processes of clinical chemistry analyses without having any significant change from the conventional method. Measurement is done using individual test tubes or cuvettes while they are transferred by a conveyor or turntable. Samples, diluents and reagents are dispensed at each station. The time for mixture, incubation and coloration is secured and then the absorbance of the reaction is measured.</td>
</tr>
<tr>
<td><strong>Portable discrete automated clinical chemistry analyzer</strong></td>
<td>A device that certainly enables to automate or mechanize manual processes of clinical chemistry analyses without having any significant change from the conventional method. Measurement is done using individual test tubes or cuvettes while they are transferred by a conveyor or turntable. Samples, diluents and reagents are dispensed at each station. The time for mixture, incubation and coloration is secured and then the absorbance of the reaction is measured.</td>
</tr>
<tr>
<td><strong>Centrifugal clinical chemistry analyser</strong></td>
<td>An automatic or semi-automatic device that transfers and mixes liquids by centrifugal force. The reaction that occurs in the centrifuge is monitored by a photometer. A separate module is required for preparation of the sample and reagents. Portable types are excluded.</td>
</tr>
<tr>
<td><strong>Mobile centrifugal clinical chemistry analyser</strong></td>
<td>An automatic or semi-automatic device that transfers and mixes liquids by centrifugal force. The reaction that occurs in the centrifuge is monitored by a photometer. A separate module is required for preparation of the sample and reagents. Portable types are excluded.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dry clinical chemistry analyser</td>
<td>An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances that occur in a reaction between chemical substances, human tissue samples, or reagents and human tissue. It measures the amount of light reflected by a reagent-impregnated test strip or multilayer film into which the sample is immersed.</td>
</tr>
<tr>
<td>Packed clinical chemistry analyser</td>
<td>An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances or human tissue samples. It performs photometric analysis of samples bonded with reagents and contained in a bag etc. The device can output graphics.</td>
</tr>
<tr>
<td>General-purpose spectrophotometric analyser</td>
<td>A device that quantifies the concentration of substances by measuring the luminous characteristics of the substance in gas or liquid. Used for diagnosis and research.</td>
</tr>
<tr>
<td>Sweat test iontophoreser</td>
<td>A device that induces perspiration, collects sweat, and analyzes chlorides or the presence/absence of chlorides and sodium. The analysis results serve as an indicator of cystic fibrosis.</td>
</tr>
<tr>
<td>Flame photometer electrolyte analyser</td>
<td>An automatic or semi-automatic device that measures electrolytes such as sodium, potassium, lithium and calcium based on the fact that several metal elements absorb.</td>
</tr>
<tr>
<td>Blood potassium analyser</td>
<td>A device that measures blood potassium ion (K⁺) concentration. The blood sample is placed on the K⁺ sensor osmosis membrane, and K⁺ spreads over the entire membrane, and permeates the ion selective electrode. The change in membrane potential is fed into the computer. The computer calculates the ion activity and converts it into the potassium activity.</td>
</tr>
<tr>
<td>Ion selective analyser</td>
<td>An automatic or semi-automatic device for various measurements based on electric potential difference using ion selective electrodes (ISE) that include external and internal reference electrodes. Some are incorporated into a general-purpose analyzer, and others.</td>
</tr>
<tr>
<td>Calcium analyser</td>
<td>A device that measures the calcium concentration of liquid samples such as whole blood, plasma, serum and urine. A calcium ion selective electrode or fluorescence quenching titration may be used.</td>
</tr>
<tr>
<td>Coulometric electrolyte analyser</td>
<td>An automatic or semi-automatic device that measures the chloride ion concentration in whole blood, plasma, serum or urine samples. Some are incorporated into a general-purpose analyzer, and others are used on their own. The device measures the chloride concentration of clinical samples by coulometric titration.</td>
</tr>
<tr>
<td>Fluorometric electrolyte analyser</td>
<td>An automatic or semi-automatic device that measures the concentration of specific electrolyte solutions such as ferrous ion by fluorometry. Some are incorporated into a general-purpose analyzer, and others are used on their own.</td>
</tr>
<tr>
<td>Protein fractionation electrophoresis analyser</td>
<td>An automatic or semi-automatic device that measures the fractionation of protein in blood, urine, cerebrospinal fluid and other body fluids. The fractionation of protein is used to assist the detection of abnormal proteins in body fluids, and genetically variant protein caused by diseases associated with tissue destruction.</td>
</tr>
<tr>
<td>Densitometry analyser</td>
<td>An automatic or semi-automatic device that measures transmitted light or reflected light from the pattern in a support medium that occurs in electrophoresis, thin-layer chromatography or immunoassay blotting sample separation for serum sample analysis.</td>
</tr>
<tr>
<td>Protein analyser</td>
<td>An automatic or semi-automatic special device used to measure concentration and to identify specific proteins generated by an immunological response. Some use the immunological response to latex.</td>
</tr>
<tr>
<td><strong>Enzyme immunoassay analyser</strong></td>
<td>An automatic or semi-automatic device that identifies substances in body fluids and measures their concentration by an enzymatic reaction in the presence of antigen/antibody conjugate. Portable types are excluded.</td>
</tr>
<tr>
<td><strong>Mobile enzyme immunoassay analyser</strong></td>
<td>An automatic or semi-automatic device that identifies substances in body fluids and measures their concentration by an enzymatic reaction in the presence of antigen/antibody conjugate. This device is a portable type.</td>
</tr>
<tr>
<td><strong>Microtitre plate reader</strong></td>
<td>A device used to read the test result indicated on the microtiter plate. The result can be printed out or displayed on the screen. Test samples are blood, reagents or mixtures. The process is also known as enzyme-linked immunosorbent assay (ELISA).</td>
</tr>
<tr>
<td><strong>Immunoturbidimetric analyser</strong></td>
<td>An automatic or semi-automatic light scattering analyzer that quantifies the analytes in the body fluid by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. Dedicated reagents are used. The device is also called a laser nephelometer. This device is a portable type.</td>
</tr>
<tr>
<td><strong>Mobile immunoturbidimetric analyser</strong></td>
<td>An automatic or semi-automatic light scattering analyzer that quantifies the analytes in body fluids by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. Dedicated reagents are used. This device is a portable type.</td>
</tr>
<tr>
<td><strong>Immunofluorescent analyser</strong></td>
<td>A device adopts a method that uses fluorescent markers in order to measure the activity of antigen/antibody. When the components of body fluids react with reagents, the device detects the intensity of fluorescence emitted from the fluorescent reagents, and measures automatically or semi-automatically the volume of antigen/antibody. Portable types are applicable.</td>
</tr>
<tr>
<td><strong>Mobile immunofluorescent analyser</strong></td>
<td>A device adopts a method that uses fluorescent markers in order to measure the activity of antigen/antibody. When the components of body fluids react with reagents, the device detects the intensity of fluorescence emitted from the fluorescent reagents, and measures automatically or semi-automatically the volume of antigen/antibody. This device is a portable type.</td>
</tr>
<tr>
<td><strong>Chemiluminescent immunoassay analyser</strong></td>
<td>An automatic or semi-automatic device that identifies and quantifies the substances in body fluids such as drugs, proteins and hormones by measuring the intensity of light emitted from the chemiluminescent substance used as a marker. Portable types are applicable.</td>
</tr>
<tr>
<td><strong>Mobile chemiluminescent immunoassay analyser</strong></td>
<td>An automatic or semi-automatic device that identifies and quantifies the substances in body fluids such as drugs, proteins and hormones by measuring the intensity of light emitted from the chemiluminescent substance used as a marker. This device is a portable type.</td>
</tr>
<tr>
<td><strong>Particle-counting immunoassay analyser</strong></td>
<td>An automatic or semi-automatic device for immunological measurement by counting latex aggregates based on the light scattering.</td>
</tr>
<tr>
<td><strong>Fecal occult blood test equipment</strong></td>
<td>An automatic or semi-automatic device that detects fecal hemoglobin by checking the light reflected by the coloration in the result of an assay such as immunochromatography.</td>
</tr>
<tr>
<td><strong>Glucose analyzer</strong></td>
<td>A device used in a laboratory to measure blood sugar (glucose) concentration.</td>
</tr>
<tr>
<td><strong>Lactate analyser</strong></td>
<td>A device that measures lactate (waste matter from muscle metabolism) concentration in biological fluids using a lactate oxidase fixed electrode and test paper, instead of using perchloric acid which is harmful in manual methods.</td>
</tr>
<tr>
<td><strong>High performance liquid chromatography analyser</strong></td>
<td>An automatic or semi-automatic device that isolates, identifies and quantifies liquid sample components such as amino acids and hormones using high performance liquid chromatography.</td>
</tr>
<tr>
<td>Analyser Type</td>
<td>Description</td>
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</tr>
<tr>
<td>Osmometric analyser</td>
<td>A device that measures the osmolar concentration (quantity of solute per unit volume) of solutions.</td>
</tr>
<tr>
<td>Laboratory refractometer</td>
<td>A device used in a laboratory to measure the refractive index (light refraction) of solutions to quantify the solute concentration in an examination sample. Usually, clinical devices have been calibrated in advance with total solids. This device indicates either protein or carbohydrate concentration.</td>
</tr>
<tr>
<td>Cholesterol analyser</td>
<td>A device that measures the cholesterol in serum/whole blood.</td>
</tr>
<tr>
<td>Bilirubinometry analyser</td>
<td>A device that measures directly or indirectly the bilirubin concentration in blood or other samples using one of 3 methods (i.e., spectrophotometry, blood fluorometry, skin spectral)</td>
</tr>
<tr>
<td>Glycohemoglobin analyser</td>
<td>A special device that measures the concentration of glycohemoglobin in human blood (HbA1c) using such methods as HPLC, electrophoresis and immunoassay.</td>
</tr>
<tr>
<td>Catecholamines analyser</td>
<td>A device that measures catecholamine concentration in biological samples.</td>
</tr>
<tr>
<td>Creatinine analyser</td>
<td>A device that measures creatinine concentration in urine or serum sample. The device measures the rate of reaction to alkaline materials by using a photodetector, and converts the rate into the concentration.</td>
</tr>
<tr>
<td>Nitrogen analyser</td>
<td>A special device that analyzes the quantity of nitrogen (N2) in biological fluids.</td>
</tr>
<tr>
<td>Portable clinical refractometer</td>
<td>A portable device used in laboratory tests to measure the optical refractive index against the light emitted to a solid/liquid. Used for measurement of blood glucose and alcohol concentration of specific urine samples.</td>
</tr>
<tr>
<td>Blood gas oxygen analyser</td>
<td>A special device used to continuously measure, monitor and display the partial oxygen pressure in human blood by using an electrochemical sensor.</td>
</tr>
<tr>
<td>General-purpose blood gas analyser</td>
<td>An automatic or semi-automatic device that identifies and quantifies 2 or more gases or electrolytes in whole blood using multiple electrodes. The device can output graphics and data.</td>
</tr>
<tr>
<td>Instrument Description</td>
<td>Details</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Coulometric carbon dioxide measuring instrument</td>
<td>A device used to measure bicarbonates/carbon dioxide in plasma, serum, or whole blood. The measurement of bicarbonates/carbon dioxide is used for diagnosis and treatment of a number of potentially serious diseases that are associated with changes in the balance of internal acidity.</td>
</tr>
<tr>
<td>Extracorporeal blood gas analyser</td>
<td>An automatic or semi-automatic device that continuously controls and monitors partial oxygen pressure in extracorporeal circulation blood (e.g., blood circulating in a closed extracorporeal circuit). Used with a cardiopulmonary bypass unit during open chest cardiac surgery.</td>
</tr>
<tr>
<td>Methane gas analyser</td>
<td>An analyzer that measures methane content in exhaled air samples. Usually, parts per million (ppm) is adopted. It utilizes electrochemical chromatography or gas chromatography. Most of these analyzers can also measure the content of hydrogen or carbon dioxide in exhaled air samples. They are used to detect an incomplete carbohydrate degradation by bacteria and dysfunction of the small intestine due to intestinal bacterial overgrowth.</td>
</tr>
<tr>
<td>In vitro oximeter</td>
<td>A photoelectronic device used to measure oxygen concentration and hemoglobin in blood samples collected from patients.</td>
</tr>
<tr>
<td>Heparin analyser</td>
<td>An automatic device that measures heparin concentration in blood samples by mixing the sample and protamine (heparin neutralizer), and quantifying the subsequent air activation coagulation by photometric measurement.</td>
</tr>
<tr>
<td>Enzyme analyser</td>
<td>An automatic or semi-automatic device that measures the enzymatic activity of the sample for diagnosis. Some are equipped with a temperature controller and other devices in order to process more than one sample sequentially by adding reagents and samples. Some are equipped with a microcomputer that calculates enzymatic activity.</td>
</tr>
<tr>
<td>Microbial component analyser</td>
<td>A device that optically measures microbially derived components such as endotoxins in plasma and serum.</td>
</tr>
<tr>
<td>Blood cell count analyser</td>
<td>An automatic or semi-automatic device that quantifies the formed elements in the blood (i.e., erythrocytes, leukocytes, and platelets) by electroimpedance, optical scattering or dye binding. The device measures the absolute numbers of erythrocytes and leukocytes in a</td>
</tr>
<tr>
<td>Hematocrit analyser</td>
<td>A device that measures hematocrit (proportion of erythrocytes) in blood samples.</td>
</tr>
<tr>
<td>Manually-operated blood cell count analyser</td>
<td>A device that functions as a manual blood cell counting chamber. The device consists of a thick glass slide with a dent of a specific depth and a grid of perpendicular lines. The blood cells of the known volume in the square covered with the cover glass are counted microscopically.</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
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</tr>
<tr>
<td>Reticulocyte analyser</td>
<td>An automatic or semi-automatic device used for quantitative and qualitative analysis of stained undifferentiated erythrocytes. It assists the diagnosis of certain types of hematopoietic diseases.</td>
</tr>
<tr>
<td>Automatic blood cell differential analyser</td>
<td>An automatic or semi-automatic device that classifies blood cells such as erythrocytes, leukocytes or platelets, and identifies the characteristics and the count of microcytes and macrocytes.</td>
</tr>
<tr>
<td>Coagulation timer</td>
<td>A device used to measure and indicate coagulation time. It automatically indicates and records the time required for coagulation of whole blood.</td>
</tr>
<tr>
<td>Blood coagulation analyser</td>
<td>An automatic or semi-automatic device that performs qualitative and quantitative analysis of hemostatic (reduce of bleeding) components such as fibrinogen, fibrin, and platelets and measures the time taken for bleeding to stop.</td>
</tr>
<tr>
<td>Thrombosis analyser</td>
<td>A device that detects the presence of blood aggregation such as thrombus formation and coagulation in blood vessels by photometric measurement.</td>
</tr>
<tr>
<td>Erythrocyte sedimentation rate analyser</td>
<td>An automatic or semi-automatic device that measures the rate of erythrocyte sedimentation (sinking), which is known as the erythrocyte sedimentation rate (ESR), in whole blood samples.</td>
</tr>
<tr>
<td>Platelet aggregation analyser</td>
<td>A device that measures the change in the shape of platelets and platelet aggregation in blood coagulation.</td>
</tr>
<tr>
<td>Platelet aggregation record analyser</td>
<td>An automatic device that records the change in the shape of platelets and aggregation over time. The device is connected to a platelet aggregation analyzer suitable for the method adopted (e.g. optical density, electroimpedance), and stores the data.</td>
</tr>
<tr>
<td>Cell analyser</td>
<td>A device that analyzes the physiological function of cells such as blood cells.</td>
</tr>
<tr>
<td>Blood smear maker</td>
<td>An automatic device used to produce blood sample film (blood smear sample) on a glass slide. It collects the sample from a test tube, transfers the microscopic slide, and adjusts the length and width of the smear sample. Some stain the blood films. Used to prepare samples optimal for laboratory analysis by avoiding contact with pathogen-containing blood samples.</td>
</tr>
<tr>
<td>Cartidge for blood coagulation test</td>
<td>A dedicated cartridge for an analyzer that measures the time taken for blood coagulation.</td>
</tr>
<tr>
<td>Chromosome analyser</td>
<td>An automatic device that indicates the blood cells in peripheral blood samples, and enables the operator to identify individual cells by type.</td>
</tr>
<tr>
<td>Hemoglobin analyser</td>
<td>A device that measures the hemoglobin in the blood by spectrophotometry.</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Viscosimetric analyser</td>
<td>A device that measures the resistance of fluid against the flow by intermolecular force. It is also used for the analysis of whole blood, serum or plasma.</td>
</tr>
<tr>
<td>Hemoximetric analyser</td>
<td>A device that measures oxygen saturation (SaO2), and the concentrations of oxidized hemoglobin (HbO2), carbon monoxide hemoglobin (COHb), methemoglobin (MetHb), and reduced hemoglobin (RHb) by using the differential absorption of light in hemolyzed blood.</td>
</tr>
<tr>
<td>Radioimmunoassay analyser</td>
<td>An automatic or semi-automatic device that quantifies such substances as hormones, vitamins, drugs, cancer antigens, enzymes, receptors, viruses, antibodies, and polypeptides in biological fluids by radioisotope labelling. The method of quantification provides the method of binding between the ligand (analyte, usually an antigen), and the ligand-specific binder (usually an antibody). The radioimmunoassay measures the amount of the analyte.</td>
</tr>
<tr>
<td>Immunoassay scintillation counter</td>
<td>A device that measures the radiation emitted from a radioactive indicator used to label biochemical samples. The radiation converted into photons by a scintillator is measured by the photomultiplier tube. Generally, the counter is used as a detector of radioimmunoassay or immunoradiometric assays for clinical use.</td>
</tr>
<tr>
<td>Hematocrit centrifuge</td>
<td>A device used in a laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. It is a desk-top device that spins at 10000 rpm or faster, rapidly processes the blood sample, and is used for separating components of a blood sample.</td>
</tr>
<tr>
<td>Blood bank centrifuge</td>
<td>A device usually used by a blood donor facility to separate components of a suspension by application of centrifugal force. It consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. Usually, it is a large, low-speed device that can dispose a large volume of donated blood.</td>
</tr>
<tr>
<td>Ultracentrifuge</td>
<td>A centrifuge used in a general-purpose laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. This is a special centrifuge that processes a relatively small number of samples at very high speed (Usually, up to 100000 rpm and RCF 800000×g).</td>
</tr>
<tr>
<td>Cytology centrifuge</td>
<td>A device used in a clinical laboratory to separate components of suspended solids by application of centrifugal force. Usually, it consists of an electrically powered drive, a vertical shaft as a part of the drive, and a horizontal rotor attached to the top end of the vertical shaft.</td>
</tr>
<tr>
<td>Cell washing centrifuge</td>
<td>A device used in a laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. The device is used for separating erythrocytes from a whole blood sample and cleaning of the blood.</td>
</tr>
<tr>
<td>Laboratory general-purpose centrifuge</td>
<td>A centrifuge used in a general-purpose laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. The device centrifuges a sample – e.g., body fluid-alone, or one to which reagents or other additives have been added before measurement of analytes. Usually, the device is used for separating components of a cell suspension.</td>
</tr>
<tr>
<td>Cell disrupter</td>
<td>A device used in a laboratory for breaking the membrane to allow direct contact with the cellular contents. Usually, a high-voltage current or an ultrasonic shock wave is used to destroy cell membranes.</td>
</tr>
<tr>
<td>Hematological separator</td>
<td>A device used in a laboratory to separate target blood cells before the selection of stem cells. One method involves using paramagnetic microspheres coated with the selected antibody. These paramagnetic microspheres, in combination with selected cells, form aggregates and separate the cells. Through various treatments in combination with centrifugal force, pressure, and membranes.</td>
</tr>
<tr>
<td>Cell/plasma haematological separator</td>
<td>Usually, an examination device used to separate various blood components such as blood cells and plasma for storage at a blood bank. It utilizes various processes such as centrifugal force, pressure, and membranes.</td>
</tr>
<tr>
<td>Serum separator</td>
<td>An examination device that separates a certain type of plasma in the primary sample, and further separates the separated matter to be used as a secondary sample.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Description</th>
<th>Definition</th>
<th>Code</th>
<th>Applicable</th>
<th>1st Access</th>
<th>2nd Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunoassay sample processor</td>
<td>A device or instrument that homogenizes the sample collected from human tissue, or produces samples for analysis using an immunoassay analyzer.</td>
<td>30870000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample processor</td>
<td>A device for pre-treatment of samples. The automatic system is equipped with various examination devices such as a control computer that pre-treats samples for sample analysis, a sample handler, a processor, or a robot. It does exclude just a simple operation.</td>
<td>38757000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood grouping haematology analyser</td>
<td>An automatic or semi-automatic device used for examination prior to blood transfusion (determination of ABO types and subtypes, Rh and other erythrocyte phenotypes, detection of antibodies, syphilis examination and hepatitis examination)</td>
<td>35635000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine analyser</td>
<td>An automatic or semi-automatic, dedicated device that identifies and measures chemical substances in the urine by photometric measurement or granule pattern recognition.</td>
<td>35918000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine gravimeter</td>
<td>A device that measures the specific gravity of urine.</td>
<td>70187000</td>
<td>applicable</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Automated urine screening system</td>
<td>An automatic urine screening system that consists of microbiology (culture media), bacteriological culture media, and urine screening (bacteriology).</td>
<td>30648000</td>
<td>applicable</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use urine flowmeter</td>
<td>A device used to measure the flow rate of urine excreted from a patient. This device is for single-use.</td>
<td>32072000</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Urinary sediment analyser</td>
<td>An automatic or semi-automatic special device that recognizes, and counts the pattern of urinary sediment by flow cytometry or the smear method.</td>
<td>33915000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nephelometric analyser</td>
<td>A device that detects scattered light only using a photodetector that is installed in the direction to form a certain angle with the incident beam coming from the light source shone toward the suspension that contains cells. Bacterial particles in a suspension can be measured.</td>
<td>15163000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yeast/fungi analyser</td>
<td>A device or a (device) system used to confirm the presence of yeast/fungi in biological samples.</td>
<td>30667000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated blood culture analyser</td>
<td>An automatic or semi-automatic device that detects the microbial growth in a blood culture medium. Some identify microorganisms. To identify pathogens, use the growth curve calculated by measuring the production rate of metabolites in a sample-containing bottle, tube, or vial. To measure the production rate of metabolites various methods are applied.</td>
<td>35617000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colony quantitative analyser</td>
<td>A device that reflects the light surface to allow an accurate count of bacterial colonies. The light surface divides the agar medium dish by a grid of perpendicular lines, and the operator can count the colonies in each grid and check the counted grids.</td>
<td>15126000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbe identification analyser</td>
<td>An automatic or semi-automatic device that identifies infectious or pathogenic microorganisms that are isolated from biological samples such as blood, urine, cerebrospinal fluid, sputum, and feces by specifying the characteristics of morphology.</td>
<td>34573000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotic susceptibility analyser</td>
<td>An automatic or semi-automatic device that identifies infectious/pathogenic microorganisms by photometry such as absorption, fluorescence and luminescence, and measures the susceptibility to therapeutic drugs.</td>
<td>34574000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bacteriological incubator</td>
<td>A device that cultivates microorganisms for examination.</td>
<td>70189000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automated cytological analysis device</td>
<td>A device that utilizes the morphology and stainability of cells, and performs cytodiagnosis by image analysis.</td>
<td>70190000</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Cryostat microtome                                                        | A device that consists of microtomes contained in a temperature controlled cabinet called a cryostat. The device enables the preparation of sections of frozen tissue samples rather than using a time-consuming, fixed procedure. This leads to rapid diagnosis.                                                                 | 15157000| 1           | 1          | N/A        | N/A
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Description</th>
<th>Code</th>
<th>I</th>
<th>1</th>
<th>N/A</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotary microtome</td>
<td>A microtome used to shave sections of tissue samples into thin slices. Usually, the sample is stabilized (fixed) with paraffin wax before being shaved off. The section is shaved off by each round of the pulley.</td>
<td>15158000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sliding microtome</td>
<td>A microtome used to shave celloidin section and large section tissue into thin slices. Usually, the sample is stabilized (fixed) with paraffin wax before being shaved off. When the sliding sledge that supports the sample holder is pushed to the top of the severing.</td>
<td>15159000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable microtome blade</td>
<td>A flat, wedge-shaped blade with a very sharp cutting edge. Usually, it is attached to a microtome which is used to prepare ultra-thin slices from paraffin-fixed tissue. This device is reusable.</td>
<td>42439000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use microtome blade</td>
<td>A flat, wedge-shaped blade with a very sharp cutting edge. Usually, it is attached to a microtome which is used to prepare ultra-thin slices from paraffin-fixed tissue. This device is for single-use.</td>
<td>42440000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
</tr>
<tr>
<td>Automated staining device</td>
<td>A device that prepares tissue samples for pathological examination and samples for cytodiagnosis and blood examination. It includes a device for staining or a device for smearing only.</td>
<td>70191000</td>
<td>1</td>
<td>-</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Cryogenic temperature control unit</td>
<td>A device that maintains a constant, extremely low temperature such as –200°C. Usually, it consists of a temperature sensor, a thermometer and electronic components. Used in cryosurgery treatment unit and other base units to preserve tissues and organs.</td>
<td>16538000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sperm/semen analyser</td>
<td>A device that measures the sperm concentration in a sample, and shows quality of the sperm activity (motility).</td>
<td>36744000</td>
<td>1</td>
<td>-</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Gene analyser</td>
<td>A device that analyzes the sequence information of nucleic acid molecules extracted from biological samples. Usually, nucleic acid molecules are amplified in order to ensure secure analysis.</td>
<td>70192000</td>
<td>1</td>
<td>-</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Flow cytometer</td>
<td>A device that passes cells in a flow cell, irradiates the cells with a laser beam, etc. and identifies/quantifies the cells based on the scattered light, intensity and type of</td>
<td>70193000</td>
<td>1</td>
<td>-</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable cholangiographic needle</td>
<td>A long, thin needle used to infuse a contrast medium into the bile duct for cholangiography. This device is reusable.</td>
<td>12739001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable hypodermic needle</td>
<td>A long, thin, hollow needle used with a syringe, secondary drug therapy set or venous dissection set (e.g., blood collection adaptor and holder) to administer liquid to patients and draw liquid from patients. This device is reusable.</td>
<td>12745001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable intra-arterial needle</td>
<td>A long, thin, hollow needle for puncturing an artery. Usually, it is made of metal. This device is reusable.</td>
<td>12747001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable tine test needle</td>
<td>Long, thin needles for making simultaneous multiple punctures in a tine test for tuberculosis. This device is reusable.</td>
<td>15679001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable filter needle</td>
<td>A long, thin, needle with a filter installed in order to filtrate the injection fluid during administration. This device is reusable.</td>
<td>16266001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable subcutaneous injection/infusion port needle</td>
<td>A long, thin, hollow needle attached to a syringe to directly inject or infuse a drug intravenously for treatment. This device is reusable.</td>
<td>17180001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable fistula needle</td>
<td>A long, thin, hollow, reusable needle used for drainage from a fistula. This device is reusable.</td>
<td>32111001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable ophthalmic cannula</td>
<td>A nonsterile cylindrical device used for the drainage and suction of intraocular substances, and infusion of perfusate in ophthalmic surgery. This device is reusable. Tips connecting to device to generate ultrasonic energy are not included.</td>
<td>34899011</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Name</td>
<td>Description</td>
<td>Code</td>
<td>Section</td>
<td>Quantity</td>
<td>N/A</td>
<td>308/367</td>
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</tr>
<tr>
<td>Reusable ophthalmic surgery cannula with tube</td>
<td>A cylindrical device with tube used for infusion of perfusate and suction of intraocular substances in ophthalmic surgery. This device is reusable.</td>
<td>34899021</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable ophthalmic surgery cannula</td>
<td>A cylindrical device used for infusion of perfusate and suction of intraocular substances in ophthalmic surgery. This device is reusable. Some have a round, flat or hook tip, and in others, the end of needle is covered with a sleeve.</td>
<td>34899031</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable blood collecting needle</td>
<td>A needle used as part of a blood collection set in order to collect blood. The dedicated needle is attached to a blood collection adaptor. This device is reusable.</td>
<td>35209001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Drug solutions double-edged needle</td>
<td>A needle sharp at both ends used to mix drug solutions in containers sealed with a rubber stopper. This device is for single-use.</td>
<td>70196000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Aeration needle</td>
<td>Usually, a needle used to feed air into the infusion solution bottle during drip infusion. Some have a tube and filter.</td>
<td>70199000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable injection needle</td>
<td>A thin metal tube with a pointed tip which is inserted through the skin to infuse or remove liquid. This device is reusable after sterilization.</td>
<td>30890000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable biopsy needle</td>
<td>A hollow cylindrical needle used to collect biopsy samples. Various diameters and tip configurations are available. Used to collect tissue samples for analysis. Some are straight, and others are curved. This device is reusable after sterilization</td>
<td>31730000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable aspiration needle</td>
<td>A long, thin, hollow needle with a pointed tip used to remove fluid from the body cavity or collect a biopsy sample. This device is reusable.</td>
<td>37462000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable blunt needle</td>
<td>A thin needle with a curved tip. It is designed to prevent damage to delicate anatomical regions during internal probing. This device is reusable.</td>
<td>37463000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>General purpose syringe</td>
<td>A syringe used to inject or extract liquid or gas. Usually it is made of glass or plastic, and consists of a scaled container and a plunger. In many cases it is used with an injection needle for drug administration or blood collection.</td>
<td>13929001</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Angiography syringe</td>
<td>A device consists of a cylinder and plunger, and is connected to a needle or catheter which is used to inject (infuse) a contrast medium into the heart, a great vessel or coronary artery in order to examine the heart and vessels by X-ray radiography.</td>
<td>15286000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Syringe tip cap</td>
<td>A cap that covers the end of a syringe. The cap is made of plastic, prevents the contents of the syringe from leaking, and maintains its sterility until the syringe is used.</td>
<td>16825000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Anaesthesia syringe</td>
<td>A hollow, cylindrical, plastic device with an injection plunger. Used with an injection needle to administer (infuse) anesthetic.</td>
<td>35387001</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
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</tr>
<tr>
<td>Medical Device</td>
<td>Description</td>
<td>Code</td>
<td>Quantity</td>
<td>Unit</td>
<td>Standard</td>
<td>Remarks</td>
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</tr>
<tr>
<td>General-purpose irrigation syringe</td>
<td>Mainly used for cleaning and flushing the body cavity. It is a hard plastic cylinder that has a rubber ball fixed at one end, and a nozzle at the other end.</td>
<td>35390000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Metered-delivery hypodermic syringe</td>
<td>A device consists of a scaled cylinder and a plunger, and is used to administer (inject) an accurately measured substance.</td>
<td>35904000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Periodontium anesthesia syringe</td>
<td>A dental cartridge syringe specifically designed to administer a local anesthetic to the periodontal ligament or bone by gradual pressurization.</td>
<td>35869000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable dental anesthesia syringe</td>
<td>A dental device used in dentistry to administer a local dental anesthetic using a prefilled cartridge and sterilized needle. This device is reusable.</td>
<td>35969000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Tuberculin hypodermic syringe</td>
<td>A device consists of a small cylinder and a plunger, has a fixed capacity, and is used for a tuberculin test.</td>
<td>35391000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Needle-less loss of resistance epidural localization syringe</td>
<td>A device used for the loss of resistance (LOR) technique in epidural anesthesia. It consists of a needleless cylinder and a plunger. Usually, made of plastic or glass.</td>
<td>70201001</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Glass injection syringe</td>
<td>An injection syringe made of glass.</td>
<td>70202000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Reusable arthrogram kit</td>
<td>A kit used to visualize the joint by X-ray radiography after a contrast medium has been injected into the joint space. This kit is reusable.</td>
<td>15316001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Biopsy puncture instrument</td>
<td>A puncture device used with a biopsy needle to collect tissue samples.</td>
<td>70216000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Reusable bone marrow collection/transfusion set</td>
<td>A kit used in combination in order to collect and transfer bone marrow. This kit is reusable.</td>
<td>33984001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable lumbar puncture kit</td>
<td>A kit used for lumbar puncture to collect spinal fluid. Usually, a spinal needle and a spinal fluid tube are included. This kit is reusable.</td>
<td>12404001</td>
<td>1</td>
<td>6-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable lumbar puncture needle</td>
<td>A sharp needle with stylet is used for spinal puncture to collect spinal fluid for diagnosis and examination. This device is reusable.</td>
<td>34583001</td>
<td>1</td>
<td>6-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable pneumoperitoneal needle</td>
<td>A long, thin, sharp, hollow, needle used to infuse gas into the peritoneal cavity or remove gas from it. This device is reusable.</td>
<td>12750001</td>
<td>1</td>
<td>6-①</td>
<td>applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

309/387
<table>
<thead>
<tr>
<th>Device Name</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Category</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reusable automatic lancet</td>
<td>A pen-shaped device used to collect blood from a capillary at a fingertip or earlobe. A pre-loaded needle protrudes automatically, and pricks the skin to a desired depth so as to yield a small amount of blood for analysis. This device is reusable.</td>
<td>37243001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT trocar</td>
<td>A surgical device with a sharp pyramidal or conical point. Used to make a puncture into a body cavity during ear, nose and throat (ENT) surgery. The assembled device is inserted in combination with a compatible sleeve that fits the lumen of the device. The trocar is removed after the puncture is made so as to create a working channel in the body cavity.</td>
<td>33678000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable amniocentesis kit</td>
<td>A packaged kit, tray or set that includes all of the devices and dressings necessary for collecting an amniotic fluid sample from pregnant women. This device is reusable after proper cleaning.</td>
<td>32685000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Endoscopic trocar</td>
<td>This device is a component of an endoscope that consists of several parts required to achieve its function. Connected to an endoscope to make a puncture into a body cavity. It has a pyramidal or conical point, and can be used in combination with a compatible trocar.</td>
<td>37144000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Trocar sleeve</td>
<td>A metal or plastic sleeve. It serves as a small tool that makes a puncture into the body cavity in combination with a trocar. The trocar is removed from the sleeve after the puncture is made to create a working channel in the body cavity. Some are equipped with a shut-off valve or port.</td>
<td>37148000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable invasive trocar sleeve fixation device</td>
<td>A device to be attached to a trocar sleeve in order to invasively fix the sleeve onto the abdominal wall. This device is reusable.</td>
<td>70221000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Noninvasive trocar sleeve fixation device</td>
<td>A device to be attached to a trocar sleeve in order to non-invasively fix the sleeve onto the abdominal wall.</td>
<td>70223000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Trocar guide rod</td>
<td>A small metal rod used to expand the working channel created in the body by inserting a large trocar sleeve of approximately 10-20 mm. This guide rod is inserted into a trocar sleeve, and the sleeve is removed while keeping the orifice airtight. A special dilator with a large sleeve is inserted along the outer surface of this guide rod, and while the hole is dilated, it serves as a guide for introducing a tube or catheter.</td>
<td>37149000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Trocar sleeve dilator</td>
<td>A hollow dilator with a tapered point used to smoothly insert a large trocar sleeve required for significantly dilating the lumen of the working channel of approximately 10-20 mm. This dilator is inserted along the outer surface of the guide rod so as to push away the sleeve.</td>
<td>37151000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Trocar housing</td>
<td>A device to be attached to a trocar sleeve. A shut-off valve or port is used to introduce gas or liquid. Some have various sizes and designs.</td>
<td>70224000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reducer for trocar</td>
<td>A device to be attached to a trocar sleeve. It reduces gas leakage during the procedure, and keeps the body cavity airtight.</td>
<td>70225000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Trocar for cardiovascular/thoracic</td>
<td>A surgical device with a sharp pyramidal or conical point that is used to make a puncture into a body cavity during cardiovascular and thoracic surgery. The assembled device is introduced in combination with a compatible sleeve that fits the lumen of the device. The trocar is removed after the puncture is made so as to create a working channel in the body cavity.</td>
<td>42401001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable subcutaneous tunneller</td>
<td>A surgical device usually made of metals such as stainless steel, or a polymeric material. It is used to create a communicating channel or a tunnel under the skin, which is intended to provide a guide path for a tube or catheter. This device is reusable.</td>
<td>35950001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Blood collecting puncture instrument</td>
<td>A puncture device used with a blood lancet to collect trace blood for self-measurement of blood glucose.</td>
<td>70226000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Item Description</td>
<td>Identification No.</td>
<td>Manufacturing Code</td>
<td>Approval Status</td>
<td>Approval Status Notes</td>
<td>Whether</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>--------------------</td>
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<td>---------</td>
</tr>
<tr>
<td>Needle guard</td>
<td>17812000</td>
<td>I 1</td>
<td>N/A</td>
<td></td>
<td>1-1</td>
</tr>
<tr>
<td>Dental syringe</td>
<td>35970011</td>
<td>I 2</td>
<td>N/A</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Single-use needle recapping device</td>
<td>36187000</td>
<td>I 1</td>
<td>N/A</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Reusable needle recapping device</td>
<td>37461000</td>
<td>I 1</td>
<td>N/A</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Fistula length measuring instrument</td>
<td>70228000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Fistula indwelling tube replacement device</td>
<td>70229000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Gastrostomy tube measuring kit</td>
<td>70230000</td>
<td>I 1</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Esophageal balloon catheter</td>
<td>34915000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Temporary use gastroesophageal sterile tube and catheter</td>
<td>70231000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Ostomy irrigation kit</td>
<td>37716000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Artificial esophageal tube</td>
<td>70247000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Laryngotracheal anaesthesia spray kit</td>
<td>70251000</td>
<td>I 2</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Hemostatic nasal catheter</td>
<td>18716000</td>
<td>I 5</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td>Reusable tube disconnecting wedge</td>
<td>44345000</td>
<td>I 2</td>
<td>applicable</td>
<td></td>
<td>0-0</td>
</tr>
<tr>
<td><strong>Nasal balloon</strong></td>
<td>A rubber balloon inflated with air or liquid to maintain the structure and patency of the nasal cavity.</td>
<td>12699000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable ENT catheter</strong></td>
<td>A tubal surgical device that secures a passage for aspiration, perfusion, and the insertion of other surgical devices. This device is reusable after cleaning and sterilization.</td>
<td>16432001</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Short-term use oropharyngeal airway</strong></td>
<td>A curved tube made of metal, plastic or rubber inserted only for oral cavity use to maintain the patency of the respiratory tract for gas exchange or aspiration, which is intended for short-term use. This device is useful for preventing the tongue from blocking.</td>
<td>70259000</td>
<td>I</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Short-term use nasopharyngeal airway</strong></td>
<td>A rubber or plastic airway inserted via the nostril into the pharynx in order to maintain the patency of the respiratory tract. No connector. This device is for single-use.</td>
<td>70260000</td>
<td>I</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Temporary use metallic urethral catheter</strong></td>
<td>A metal tube used to drain urine retained in the urinary bladder.</td>
<td>70262000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Endoscope/arthroscope connection tube</strong></td>
<td>A tube connected to an endoscope or arthroscope during endoscopic surgery or examination.</td>
<td>70267000</td>
<td>I</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Protective stopcock</strong></td>
<td>A lid-like plastic item used to prevent content leakage from the tool, and maintain sterility of the contents until use. This item is for single-use.</td>
<td>70280000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Vascular catheter cuff</strong></td>
<td>A device applied to the insertion site of a vascular catheter in order to support the prevention of infection by the effect mainly on the growth of subcutaneous tissue. General-purpose types are excluded.</td>
<td>17470009</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Guidewire insertion connector</strong></td>
<td>A guidewire connected to the connector of a catheter, etc. and assists the insertion of a guidewire into the body. This is not inserted into the body, nor used for the administration of drug solutions.</td>
<td>70286000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Intravascular catheter with valve cutter</strong></td>
<td>A flexible tube with a blade that is inserted into the resected vein, and used to dissect the venous valve without any damage, and eliminate its function in revascularization by bypass transplantation in which peripheral veins are used for arteries.</td>
<td>70299000</td>
<td>I</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Renal auxiliary cooling catheter</strong></td>
<td>A catheter used to infuse the chilled perfusate into the kidney from the renal artery via the catheter in order to preserve the kidney after cardiac arrest.</td>
<td>70300000</td>
<td>I</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cerebrospinal fluid drainage circuit</strong></td>
<td>A drainage circuit connected to the drain tube placed for discharging cerebrospinal fluid.</td>
<td>34586001</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Shunt valve adjustment tool</strong></td>
<td>A tool used to noninvasively confirm or change non-invasively from outside the body the pressure of the pressure-adjustable shunt valve used for hydrocephalus treatment. Usually, a permanent magnet is used to select the pressure of the adjustable valve.</td>
<td>70305000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Item Name</td>
<td>Description</td>
<td>Code</td>
<td>Applicability</td>
<td>Unit</td>
<td>Notes</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------</td>
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<td>------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Drainage bag</strong></td>
<td>A plastic drainage bag that consists of 1 or 2 chambers, and is connected to a drain tube. It is connected to a thoracic or abdominal cavity drain, and used to eliminate blood, air, and purulent matter from the thoracic or abdominal cavity.</td>
<td>70308000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Temporary use umbrella catheter</strong></td>
<td>A flexible tube with a diaphragm at the distal end that opens when a catheter (e.g., barium enema umbrella catheter) is inserted into a body orifice for temporary use.</td>
<td>10760001</td>
<td>I</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Single-use nasal dropper</strong></td>
<td>A hollow tube used for aspiration of a small amount of liquid, and to administer the liquid drop by drop into the nasal tube. Both ends are open, and an aspiration valve is usually attached to one end. Usually made of glass or plastic. This device is for single-use.</td>
<td>35215000</td>
<td>I</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Single-use dental suction cannula</strong></td>
<td>A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is for single-use.</td>
<td>37434000</td>
<td>I</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Reusable dental suction cannula</strong></td>
<td>A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is reusable.</td>
<td>38759000</td>
<td>I</td>
<td>6-①</td>
<td>applicable N/A</td>
</tr>
<tr>
<td><strong>Catheter holder</strong></td>
<td>An extracorporeal tool that is attached to a venous catheter or injection needle to protect the insertion part and prevent the venous tool from falling accidentally.</td>
<td>15735000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Shunt holder</strong></td>
<td>A holder used to stabilize (fix) the blood access tool for hemodialysis or other purposes.</td>
<td>32133000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Crimp for plier</strong></td>
<td>A manual tool that consists of two rods having a handle at each proximal end extending to the distal end through a pivot point. The tips serve as pliers, and are used to manipulate the arteriovenous shunt of patients required hemodialysis.</td>
<td>32139000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Catheter connector</strong></td>
<td>A tool used to connect the catheter to another object such as a container, or insert the catheter into the body for irrigation or drainage.</td>
<td>32339000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Esophageal intubation detector</strong></td>
<td>A device that detects esophageal intubation by using a syringe or valve in order to suck through the tracheal tube inserted into the patient via a tube piece (e.g., other small pieces).</td>
<td>36290000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Angioplasty balloon inflator</strong></td>
<td>A hand-held device (e.g., syringe or small pump) with a manometer used for balloon pressurization when a balloon catheter for angioplasty is placed in the body. The pressure occurring during coronary artery dilation (also known as percutaneous transluminal)</td>
<td>17541010</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Non-vascular balloon inflator</strong></td>
<td>A hand-held device (e.g., syringe or small pump) with a manometer used for balloon pressurization when a balloon catheter is placed in the body.</td>
<td>17541020</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable tracheal tube stylet</strong></td>
<td>A device used to stabilize a tracheal tube, and facilitate passage through the vocal cords. Usually, made of flexible metal. It is inserted into the tracheal tube before intubation. In order to prevent damage to the trachea during insertion, it is removed after intubation is used.</td>
<td>35402000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable tracheal introducer tube</strong></td>
<td>A device used to introduce a tracheal tube for intubation. A long, thin, rod-like device with a curved tip that usually allows adjustment of the tube in a favorable direction for routine or difficult oral intubation. This device is reusable.</td>
<td>36131000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Single-use tracheal tube stylet</strong></td>
<td>A device used to stabilize a tracheal tube, and facilitate passage through the vocal cords. Usually made of flexible metal. It is inserted into the tracheal tube before intubation. In order to prevent damage to the trachea during intubation, it is inserted into the tracheal tube before intubation.</td>
<td>37469000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Single-use tracheal introducer tube</strong></td>
<td>A device used to introduce a tracheal tube for intubation. A long, thin, rod-like device with a curved tip that usually allows adjustment of the tube in a favorable direction for routine or difficult oral intubation. This device is for single-use.</td>
<td>41829000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Reusable tracheal tube guide</strong></td>
<td>A device used as a guide when replacing a tracheal tube placed in the patient. The guide is inserted into inside of the tube placed in the body, and the tube is removed by sliding it along the guide. In order to facilitate the correct insertion of the new tracheal tube, the guide is removed.</td>
<td>42075000</td>
<td>I</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Marked for use</td>
<td>Item Code</td>
<td>Marked for use</td>
<td>Item Code</td>
</tr>
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</tr>
<tr>
<td>Single-use tracheal tube guide</td>
<td>A device used as a guide when replacing a tracheal tube placed in the patient. The guide is inserted into inside of the tube placed in the body, and the tube is removed by sliding it along the guide. In order to facilitate the correct insertion of the new tracheal tube, the new tracheal tube is inserted by sliding it along the guide. The guide is removed when the tube is closed.</td>
<td>5-①</td>
<td>applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter clamp</td>
<td>A device that is used to hold or pressurize the catheter. The pressure is applied until the catheter is closed.</td>
<td>1</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable tubing clamp</td>
<td>A device that is used to block or pinch the tube. Usually, it is used in laboratories. Some are for general-purpose use and are used in medical institutions. This device is reusable.</td>
<td>1</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Tube cuff spreader</td>
<td>A device that is used in to attach the tracheal tube cuff to the tracheal tube or tracheal cannula.</td>
<td>6-①</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Temporary use catheter balloon repair kit</td>
<td>A kit that contains adhesives and balloons used temporarily for repair or replacement of a catheter balloon.</td>
<td>5-①</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable catheter controller steering unit</td>
<td>A unit that is connected to the proximal end of an operable guidewire in order to control an operable catheter. This device is reusable after proper cleaning and sterilization.</td>
<td>12</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion stopcock</td>
<td>A stopcock that is used to adjust the infusion of fluid into the vascular system. It is included in a vascular administration kit. This item is for single-use.</td>
<td>2</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Enteral nutrition infusion stopcock</td>
<td>A stopcock that is used to adjust the infusion of fluid into the gastrointestinal tract. It is connected to a catheter for enteral feeding.</td>
<td>2</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>General-purpose stopcock valve</td>
<td>A valve that is used to control the direction of flow of a liquid or gas. Usually, it is made of durable materials (e.g., plastic, metal) and is used for various purposes. It is not connected to an active device.</td>
<td>2</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Tracheal tube cuff inflator</td>
<td>A device that supplies air to the cuff of a tube when a tracheal tube is placed in the body. Usually, it is equipped with a rubber ball that supplies the air. Most of them are equipped with a manometer that indicates the pressure so as to prevent overinflation of the</td>
<td>1</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Drug solution needle</td>
<td>A liquid collection needle that is attached to a syringe, and used to draw up a drug solution from a container. Usually made of plastic or metal. Some have a filter.</td>
<td>1</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Infusion accessory set</td>
<td>A set of accessories used with an infusion set. It contains caps, connectors, and adaptors.</td>
<td>2</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Catheter fixation patch</td>
<td>A patch having adhesive on one side, and a catheter holder on the other side, and which is used to allow an arterial, central venous, or epidural catheter to be fixed easily.</td>
<td>1</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Catheter sterile sleeve</td>
<td>A device that covers a sheath to make it easier to perform an aseptic procedure with an imaging tool in this device.</td>
<td>1</td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable arthroscopy catheter</td>
<td>A flexible tube used for arthroscope examination in the joint. This device is reusable.</td>
<td>6-①</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Description</th>
<th>Code</th>
<th>Class</th>
<th>Category</th>
<th>Applicable Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubing for suction</td>
<td>A plastic tube used to connect an aspirator or a drain tube to a collection container when aspirating effusions that need to be removed.</td>
<td>16779000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Lacrimal tube</td>
<td>A tube used to collect tears for diagnosis and examination.</td>
<td>17003000</td>
<td>1</td>
<td>5-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Balloon hemostasis</td>
<td>An inflatable balloon to be inserted into the nasal cavity and expanded to stop blood by pressure. This balloon is inflated with air or liquid. This device is for single-use.</td>
<td>31911000</td>
<td>1</td>
<td>5-3</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Insemination uterine catheter</td>
<td>A semi-rigid or rigid tube used to inject seminal fluid into the uterus. This device is for single-use.</td>
<td>34077000</td>
<td>1</td>
<td>5-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Single-use ear catheter</td>
<td>A semi-rigid or rigid, plastic tubal surgical device inserted into the ear canal. This catheter is left in the place as a guide path for aspiration, irrigation, or insertion of other surgical devices. This device is for single-use.</td>
<td>34897000</td>
<td>1</td>
<td>5-3</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Hemostatic transnasal catheter</td>
<td>A curved tube including a stylet that is used to block the choana for stopping nasal bleeding by attaching a spring.</td>
<td>35790000</td>
<td>1</td>
<td>5-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Infusion extension tube</td>
<td>A tube used to extend a drip infusion line.</td>
<td>12170001</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Ophthalmic perfusion/aspiration tube</td>
<td>A set of tubes used for perfusion/aspiration devices in ophthalmic surgery.</td>
<td>70339000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Temporary use laryngotomy tube</td>
<td>A tube that is temporarily used to secure the airway of patients undergoing partial or total laryngectomy. This is nonsterile.</td>
<td>70343000</td>
<td>1</td>
<td>5-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Cervical dilator</td>
<td>A catheter that is used to dilate the cervical canal with a balloon when the uterine does not dilate enough due to inertia uteri.</td>
<td>70344000</td>
<td>1</td>
<td>5-1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Orthopaedic drainage cannula</td>
<td>An orthopedic drainage cannula. This does not fall under the classification of other cannulas.</td>
<td>70352000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Insufflation tube</td>
<td>A flexible tube used to connect the insufflation device and insufflation needle or trocar. Some include a filter.</td>
<td>70353000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Exhaust tube</td>
<td>A flexible tube used to connect a gas suction unit of an insufflation device and an endoscopic treatment tool or trocar.</td>
<td>70354000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Water supply or suction tube for endoscope</td>
<td>A flexible tube used to connect the water feed unit or aspiration unit to the endoscope or endoscopic treatment tool.</td>
<td>70355000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Device Description</td>
<td>Definition</td>
<td>Code</td>
<td>Quantity</td>
<td>Basis of Use</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Air and water supply tube</td>
<td>A flexible tube used to connect the water feed unit or air supply unit to the endoscope or endoscopic treatment tool.</td>
<td>70356000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Blood sampling suction unit</td>
<td>A simple auxiliary aspirator that consists of a housing, plunger and gasket. Usually, it assists trace bleeding by generating negative pressure on a puncture site so that patients can measure their blood glucose levels themselves.</td>
<td>70362000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Evacuated blood collecting tube holder</td>
<td>A holder that is included in a vacuum blood collection system. It is used for fixation and stabilization upon puncturing blood collection needle etc. After fitting and fixing the blood collection needle, the vacuum blood collection tube is inserted into this holder to start evacuation.</td>
<td>70364000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Blood sampling/transfusion tube heat fusion joint device</td>
<td>A device used in a way that a blood collection set or blood transfusion tube set and the tube to be connected to those tube sets are severed with a heated blade and the tubes are moved while the severed section is still touching the blade. The heated blade is then used to connect the tubes.</td>
<td>70366000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Tissue culture sample preparation container</td>
<td>A container used to prepare the blood components which are necessary for tissue cultivation. The containers also refer to it as the bags for storing and separating plasma and serum derived from human and animal.</td>
<td>70369000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Gravity pour infusion administration set without needle</td>
<td>An infusion set (no needle) used to administer fluid infusion by gravity without using any active device. A needle or butterfly needle is connected to the head.</td>
<td>70370000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable winged needle for general veins</td>
<td>A very thin, sharp needle used for veins in general. This device is reusable.</td>
<td>70377000</td>
<td>1</td>
<td>6-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Reusable winged scalp vein needle</td>
<td>A very thin, sharp needle used for scalp veins or other small veins (pediatric use in particular). This device is reusable.</td>
<td>35211001</td>
<td>1</td>
<td>6-1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Container adaptor</td>
<td>An adaptor (usually, a small part) used to connect a container to an extracorporeal component (usually, infusion line) for infusing a drug solution or draining body fluid. Usually, it is used to connect components from different manufacturers. This device is for connecting components from different manufacturers.</td>
<td>44035000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Fluid transfer tube set</td>
<td>A set of devices used to transfer an infusion solution from a container to an intravenous infusion bag or other containers for infusion solution.</td>
<td>16610000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Intravenous line connector</td>
<td>A device that is inserted into a Y-shaped connection site on the venous line for drug administration or blood collection.</td>
<td>17501000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Drug solution preparation needle</td>
<td>A device used to transfer a drug from one container to another container. Some are equipped with a tube, plastic or metal needle for connecting or inserting into the container.</td>
<td>70379000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Liquid transfer device set</td>
<td>A set of devices used to transfer an infusion solution from a container to an intravenous infusion bag or other containers for infusion solution.</td>
<td>70380000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Drug solution preparation instrument</td>
<td>A device used to transfer a drug solution from one container to another container. Some are equipped with a tube or spike for connection/insertion into the container.</td>
<td>70381000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Infusion line clamp</td>
<td>A tool used to block or pinch a tube line (e.g., infusion set, aspirator tube) in order to stop the passage of a substance in the line. This tool is reusable.</td>
<td>32146000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Item Description</td>
<td>Code</td>
<td>Usage</td>
<td>Applicability</td>
<td>Details</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>--------</td>
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<td>---------------</td>
<td>-------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use in-line backflow check valve</td>
<td>34099001</td>
<td>1</td>
<td>2</td>
<td>Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use infusion solution container</td>
<td>35127000</td>
<td>1</td>
<td>2</td>
<td>Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dial-calibrated infusion line clamp</td>
<td>35894000</td>
<td>1</td>
<td>1</td>
<td>Applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable in-line backflow check valve</td>
<td>42548001</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable uterine injector</td>
<td>15622000</td>
<td>1</td>
<td>5</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraosseous drug infusion kit</td>
<td>18009000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental medication injector</td>
<td>70387000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laryngeal injection kit</td>
<td>33427000</td>
<td>1</td>
<td>5</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable dye injector</td>
<td>17660001</td>
<td>1</td>
<td>6</td>
<td>Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Notes:*
- Some devices are applicable, while others have parameters noted as N/A or not applicable.
<p>| Reusable indicator injector | A device used to ensure accurate bolus injection of the indicator drug (e.g., chilled saline solution) into the bloodstream. Usually, used to infuse an indicator drug into the heart in order to assess blood flow in the heart. Some are used with a densitometer or thermodilution device to measure cardiac output. This device is reusable. | 31736001 | 1 | 6-① | applicable | N/A |
| Preparation drug solution injection connector | A device attached to a blood bag or drug solution container to infuse/drain a drug solution in the bag or drug solution container. | 70396000 | 1 | 2 | N/A | – |
| Drug injector testing equipment | A device/instrument used to confirm that drug injectors (e.g., infusion pump, syringe pump, infusion controller) are functioning normally. Usually, used to check the flow rate, bolus, and alarm function. | 36794000 | 1 | 1 | applicable | – |
| Infusion connecting tube | A coupling tube that has a connection part at both ends to be connected to a drug solution bottle or other items. It is used to transfer the solution in the bottle for infusion. | 70399000 | 1 | 2 | applicable | – |
| Set for nutrition infusion | A device that is connected to a catheter inserted into the stomach or intestine for infusion of enteral nutrition. | 70400000 | 1 | 2 | N/A | – |
| Plasma thawing unit | A device used to thaw the frozen plasma stored by the blood bank, etc. under control before use. Various means such as a microwave oven and warming bath can be utilized. | 43434000 | 1 | 1 | applicable | – |
| Single-use luer adaptor | An adaptor used to hold multiple components used in combination in a fixed position or to connect multiple components. This device is for single-use. | 35075000 | 1 | 1 | applicable | – |
| Adaptor for syringe/needle | An adaptor that is used to connect a syringe or injection needle to a tube, stopcock, or other structure. Some are luer lock type, others are luer slip type. Some are equipped with a tube or syringe. | 35384000 | 1 | 1 | applicable | – |
| Single-use pin-indexed system adaptor | An adaptor that locks two components which are mutually compatible. The pin index is a system that consists of coded pins and holes, and serves as a safety system that allows the connection to be made only when they match and prevents inadvertent connection of the device. | 35897000 | 1 | 2 | applicable | – |
| Reusable hemostatic clip applier | A surgical device used to allow the use of hemostasis clips for blood vessel ligation. This device is reused after cleaning and sterilization. Some are used for endoscopy. | 35798000 | 1 | 6-① | N/A | N/A |
| Reusable ligation/fixation clip applier | A surgical device used to allow the use of clips for luminal tissue ligation and fixation. This device is reused after cleaning and sterilization. Some are used for endoscopy. | 70406000 | 1 | 6-① | N/A | N/A |
| Needle holder | A surgical device with handles, that is designed to hold the suture needle when suturing. The edge of the blade from the distal end to the pivot point comes in various configurations. | 12726010 | 1 | 6-① | N/A | N/A |
| Single-use needle holder | A surgical device with handles, that is designed to hold the suture needle when suturing. The edge of the blade from the distal end to the pivot point comes in various configurations. This device is for single-use. | 12726020 | 1 | 1 | N/A | – |
| Umbilical ligator | A surgical device used for umbilical cord ligation. Usually, it consists of a long shaft or cannula with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operate the clamp or grip at the distal end. | 15041000 | 1 | 6-① | N/A | N/A |
| Ophthalmic suture needle | An ophthalmic needle used to suture ocular tissues. | 32763000 | 1 | 6-① | N/A | – |</p>
<table>
<thead>
<tr>
<th>Device Name</th>
<th>Description</th>
<th>Code</th>
<th>Type</th>
<th>Quantity</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture needle</td>
<td>A needle used to insert and pull out a suture thread from the tissue. Some are designed for special functions, and other are for general-purpose.</td>
<td>70417001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Cervical cerclage needle</td>
<td>A solid cylindrical device that comes in various diameters. It has various configurations at the distal end. The solid cylindrical device is used for reefing around the cervical canal with suture materials of various types. It comes in various diameters and configurations.</td>
<td>32600000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Clincher</td>
<td>A device that automatically makes a surgical knot, and can move the knot.</td>
<td>70418000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ligator</td>
<td>A surgical device used for ligation of a blood vessel or other physical structures. It consists of a long shaft or cannula with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operates.</td>
<td>12332000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable automatic suture unit</td>
<td>A device that performs automatic suturing with a sterilized thread and repairs the damaged site or muscular damage. This device is reusable.</td>
<td>15065001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable arthroscopic suture unit</td>
<td>A device used to repair a damaged site or muscular damage. Under a controlled arthroscope, its suture punch system makes the number of stitches that the surgeon desires at the injured or damaged site. This device is reusable.</td>
<td>17735001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical stapler</td>
<td>A surgical device used for surgical stapling (some have tear-off function). Some are designed like a pistol. Some are used for endoscopy. Active types are excluded. This device is reusable.</td>
<td>32369001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Wire/ligature passer</td>
<td>A surgical device used to pass wire or ligation thread through tissue. Usually, it is either a flexible or rigid rod with a handle that has a hook, catch or clasp that holds the material to be passed through the tissue. It is tapered, and has a button or acorn-shaped item at the proximal end.</td>
<td>32864001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Endotherapy suturing device</td>
<td>A device used with a special endoscope for endoscopic treatment. Used for mechanical work such as closure of wounds and cuts with various materials (e.g., silk, catgut suture)</td>
<td>34078000</td>
<td>1</td>
<td>5-①,6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical coarctation clamp</td>
<td>A scissors-like surgical device with ring handles. The two cutting blades from the distal end to the pivot point are either straight or curved. The center of the cutting blade has a groove from one end to the other end that does not have teeth in order to prevent damage to the blood vessel held by the device.</td>
<td>35594000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Removable reusable skin staple handle</td>
<td>A reusable handle used in combination with a pistol-like mechanism and detachable skin staples with single-use.</td>
<td>35884001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Suture passer</td>
<td>A surgical device used to pass the suture thread and suture needle through the tissue. Usually, it is a flexible or rigid rod with a handle that has a hook, catch or clasp that holds the material to be passed through the tissue.</td>
<td>37839001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable staple remover</td>
<td>A metal or plastic surgical device used to remove staples from a surgical wound or dissected site. This device is reusable.</td>
<td>16787001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Clip remover</td>
<td>A surgical device that looks like scissors or tweezers, and has two blades fixed at the proximal end or in the middle. The blades are designed to hold the clip, and release when used.</td>
<td>10895000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical bronchus clamp</td>
<td>A surgical device used to place pressure on the bronchus nontraumatically.</td>
<td>34950000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical bulldog clamp</td>
<td>A surgical device that has a saw-like bite that is either linear, oblique or curved. Used to hold, connect, press or support the organs, blood vessel or tissue. The handles are either straight or ring in shape.</td>
<td>34951000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical hemorrhoid clamp</td>
<td>A scissors-like surgical device that has ring handles. The two blades from the distal end to the pivot point have a saw-like bite and a triangular point. This device is reusable after sterilization.</td>
<td>34952000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical tube clamp</td>
<td>A surgical device used to press a tube. This device is reusable after sterilization.</td>
<td>34954000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Description</td>
<td>Function</td>
<td>Code</td>
<td>Subcategory</td>
<td>Country Code</td>
<td>Newly Developed</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Reusable surgical rectal clamp</td>
<td>A surgical device used to hold, connect, press or support the rectum, rectal valve or anal tube nontraumatically. This device is reusable.</td>
<td>35542001</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical carotid clamp</td>
<td>A surgical device used to press the carotid artery. This device is reusable.</td>
<td>35593001</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable implantable vascular clip</td>
<td>A device designed to block the blood flow of a small vessel by pressurization. This device is reusable after sterilization.</td>
<td>35640001</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical tape</td>
<td>Belt-like or tubal threads and strings used to temporarily hold organs. Some have a needle.</td>
<td>70419000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-surgical esophageal varices ligation therapy ligator set</td>
<td>A set used for esophageal varix ligation in non-surgical endoscopic variceal ligation. It consists of a transparent hood and a rubber or elastomer O-ring band which is connected to the end of esophagoscope for variceal ligation.</td>
<td>70420001</td>
<td>1</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable non-sterilized scalp clip</td>
<td>A nonsterile surgical device that consists of two blades fixed in the center or an alpha-shaped unit. Used for hemostasis on the scalp during surgery. This device is reusable.</td>
<td>34959001</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable skin clip</td>
<td>A surgical device that consists of two blades fixed in the center or an alpha-shaped unit. Used to connect the edges of dissected skin or fix electrodes on the skin during surgery. This device is reusable.</td>
<td>37699000</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical wound clip</td>
<td>A metal device used to temporarily gather the edges of a wound together.</td>
<td>38144000</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable aneurysmal suture needle</td>
<td>A metal device with a sharp point that has a handle, and used to ligate blood vessels. This device is reusable.</td>
<td>34608000</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Suture retention device</td>
<td>Devices including a fixation bridge, surgical button and thread support used to ensure wider distribution of the tension of suture thread and assist the healing of the wound.</td>
<td>33519000</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Esophageal ligator</td>
<td>A surgical device used for esophageal ligation. It consists of a long shaft or catheter with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operates the clamp or grip at the distal end.</td>
<td>34137000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Haemorrhoid ligator</td>
<td>A surgical device for hemorrhoid ligation. Usually, it consists of a long shaft or catheter with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operates the clamp or grip at the distal end.</td>
<td>35157000</td>
<td>1</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical punch</td>
<td>A surgical device used to create a hole for suturing or connecting tissues or blood vessels. This device is reusable.</td>
<td>35285001</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Suture guide</td>
<td>A device placed on an open wound to guide the surgeon when deciding on the suture position. It is pulled tight to ensure that the suture threads are connected.</td>
<td>36129000</td>
<td>1</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Name</td>
<td>Description</td>
<td>Catalog Number</td>
<td>Primary Code</td>
<td>Category Code</td>
<td>Category Code Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>Needle driver</td>
<td>A device used to manipulate the suture needle in abdominal surgery. The curve of the suture needle at the shaft end is controlled by the handle.</td>
<td>70427000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Vasovasostomy set</td>
<td>A set of needle and plates that is used to fix the end of vas deferens to the plate using the needle in the (microscopic) vasovasostomy.</td>
<td>70428000</td>
<td>1</td>
<td>6</td>
<td>① N/A</td>
</tr>
<tr>
<td>Prostatectomy urinary suture guide</td>
<td>A metal device that is used to facilitate positioning of the suture after prostatectomy. Some have a balloon catheter for single-use.</td>
<td>70429000</td>
<td>1</td>
<td>5</td>
<td>① N/A</td>
</tr>
<tr>
<td>Urinary incontinence suturing needle</td>
<td>A device used to lift up the female urinary bladder neck with a thread in order to treat urinary incontinence.</td>
<td>70430001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical dressing</td>
<td>Cover and protective materials in suitable sizes used for post-operative wounds.</td>
<td>34654000</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Skin adhesive</td>
<td>A skin adhesive used for closure, connection or reinforcement of skin wounds. Made of acrylate or other synthetic substances.</td>
<td>33492101</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Angiography surgical drape</td>
<td>A cover used exclusively for angiography. This device is for single-use.</td>
<td>16006000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use general-purpose surgical drape</td>
<td>A drape made of non woven fabric used as a protective cover or curtain in order to isolate the surgical dissection site and surgical site from contamination in the operating room and catheter room (surface of devices and tables). This is also used to protect the patient from heat, flame or other morphological energy during surgery. This device is for single-use.</td>
<td>35531000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Laser-resistant surgical drape</td>
<td>A surgical drape that is specifically processed or coated with materials for protection against laser energy at the typical surgical level. This can be used to protect devices, instruments, and the patient.</td>
<td>36008000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Cast construction material</td>
<td>A tool that consists of hard protection materials (cast) made of plastic, glass fiber, or plaster for fixation of fractures, diseased joints or painful sprains.</td>
<td>33056000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Toe separator</td>
<td>A device that consists of U-shaped channels attached to a frame or a plate, or a U-shaped channel set. Used to hold individual phalanges at desired positions.</td>
<td>13544000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bunion shield</td>
<td>A pad used to protect a bunion that has formed at the root of the big toe.</td>
<td>13565000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Hand/finger splint</td>
<td>A splint used to fix a damaged hand or finger.</td>
<td>16210000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Inflatable extremity splint</td>
<td>A sleeve to be placed around the arm or leg and inflated to support and protect the arm or leg.</td>
<td>32302000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Splint for intranasal septal</td>
<td>A device made of biomaterial or synthetic material. Used for replacement or repair of the septum that separates the nasal cavities at the middle surface.</td>
<td>34005000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Description</td>
<td>Code</td>
<td>Class</td>
<td>Naturalness</td>
<td>Applicable</td>
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<td>------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Moulded splint A splint that is used to support and protect a damaged body part.</td>
<td>35354000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Single-use padded splint A padded splint that is used to support a damaged body</td>
<td>35357000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>part. This device is for single-use.</td>
<td></td>
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</tr>
<tr>
<td>Vacuum mouldable splint A splint that is used to support and protect an injured</td>
<td>35358000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>body part. The splint is placed around the affected site. The air is deflated in</td>
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<tr>
<td>order to support and protect the affected site.</td>
<td></td>
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</tr>
<tr>
<td>External nasal splint A splint that is used to support a fractured or treated</td>
<td>35411000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>nasal bone. It is placed outside the nose, functions like a truss and supports the</td>
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<tr>
<td>nose.</td>
<td></td>
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</tr>
<tr>
<td>Mouldable splint A splint that is used to support and protect a damaged body part.</td>
<td>36204000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>It is formed so as to fit the affected body part.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Reusable first aid emergency kit without medication A kit that consists of</td>
<td>43000000</td>
<td>I</td>
<td>6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>emergency items and materials for first aid treatment. Usually, it is used at a</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>facility, in the home, in a car, in an ambulance, and at places where crowds</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>gather. The kit does not include drugs. This kit is reusable after properly</td>
<td></td>
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</tr>
<tr>
<td>washing the reusable items, and replenishing consumables.</td>
<td></td>
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</tr>
<tr>
<td>Reusable first aid emergency kit with medication A kit that consists of emergency</td>
<td>44039000</td>
<td>I</td>
<td>4,6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>items and materials for first aid treatment. Usually, it is used at a facility,</td>
<td></td>
<td></td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>in the home, in a car, in an ambulance, and at places where crowds gather. The kit</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>includes drugs and components that can work as pharmaceuticals when used.</td>
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</tr>
<tr>
<td>Burn dressing A wide, layered gauze pad used to cover and protect burned skin,</td>
<td>11322101</td>
<td>I</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>and absorb the exudate from the burn.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flocculent dressing A pad made of cotton, synthetic fiber, hydrophilic polymer,</td>
<td>11751000</td>
<td>I</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>etc. used to cover wound of skin or oral mucosa. The pad for wounds of oral</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>mucosa can be used temporarily or in short term.</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Visceral retainer A wide, thin, flat pad or net with a string or a cord at one</td>
<td>13371000</td>
<td>I</td>
<td>6-①</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>end, usually made of flexible plastic. This device is used to hold an organ at the</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>proper position. It is also implanted into a surgical site temporarily. This device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>is for single-use.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin barrier adhesive plate An adhesive plate that is placed on the skin to</td>
<td>31071000</td>
<td>I</td>
<td>4</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>protect it from external contamination.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression dressing A covering material that is used to apply pressure to an</td>
<td>34084000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>affected site and prevent the body from retaining fluid. Most commonly, it is</td>
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<tr>
<td>used for transplanted skin and the treatment of burns.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burn wrap A nonsterile covering material used to cover a wound and maintain the</td>
<td>36093000</td>
<td>I</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>condition of a burn patient being transferred to a burn center or hospital. The</td>
<td></td>
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<tr>
<td>material is used at the site of an emergency. It cools the burn, moisturizes the</td>
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<tr>
<td>affected site, prevents exacerbation of the burn, minimizes trauma, and prevents</td>
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<tr>
<td>contamination. The material can be coated with a gel. It comes in various sizes</td>
<td></td>
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</tr>
<tr>
<td>(towel to bed-sheet size).</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Item Name</td>
<td>Description</td>
<td>Code</td>
<td>Quantity</td>
<td>Applicable</td>
<td>Available</td>
</tr>
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</tr>
<tr>
<td>Skin approximation tape</td>
<td>A cloth or plastic tape coated with adhesive on one side. Used for closure, connection and reinforcement of a skin wound.</td>
<td>70438000</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Catheter dressing</td>
<td>A sterilized cover/protective material such as adhesive film materials, which is directly applied to the puncture site of needle or catheter for fixation. Non-woven cloth may be added for enhanced fixation and retention.</td>
<td>70444000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Wound depth measuring instrument</td>
<td>A non-invasive probe which is applied to the body surface for a short period in order to measure the size (width) and depth (difference between the normal skin and wound) of the wound or pocket. For contact with an open wound on the skin, it should be sterilized and used only once.</td>
<td>70445000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Wound area measuring instrument</td>
<td>A device used to measure and record the area of a wound. It includes recording sheets to record the size of the wound. The recording sheets may be used in combination with the area calculator to calculate the area of the wound. For contact with an open wound on the skin, it should be sterilized and used only once.</td>
<td>70446000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Single-use class I surgical procedure kit</td>
<td>A prepackaged kit that contains all the Class I devices, cover and protection materials and drugs which are necessary for general treatment. This kit is for single-use.</td>
<td>33961001</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic foreign body extractor magnet</td>
<td>A device used to remove magnetic, metal foreign objects from the eye. It contains a permanent magnet.</td>
<td>35495000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ultrasonic nebulizer</td>
<td>A device that supplies aerosolized water or drugs generated by mechanical oscillation. It consists of an aerosol generator, reservoir, and baffle.</td>
<td>12719000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>Heated nebulizer</td>
<td>A device that supplies aerosolized water or drugs generated by heating. It consists of an aerosol generator, reservoir, and baffle.</td>
<td>12716000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>Medication spray bottle</td>
<td>A container with a spray nozzle used to spray a drug (e.g., nasal spray)</td>
<td>16529000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-heated humidifier</td>
<td>A unit used to add vapor to a dry gas. Usually, it has a reservoir and tube (to bring a gas flow and water into contact with each other). Generally, it is used with a nasal cannula.</td>
<td>35113000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-heated nebulizer</td>
<td>A device that supplies aerosolized water or drugs generated without heating (excluding mechanical oscillation). It consists of an aerosol generator, reservoir, and baffle.</td>
<td>35457000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>ENT nebulizer</td>
<td>A device that supplies aerosolized water or drugs for the patient to inhale.</td>
<td>70451000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>Gas warmer</td>
<td>A device that warms the gas used to administer oxygen or drugs to the lungs in oxygen therapy or compressed air therapy.</td>
<td>70452000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable vaginal applicator</td>
<td>A device used to apply drugs, pharmaceutical products for vaginal treatment, or to attach or apply other medical tools in the vagina. The hand-held valve (e.g., manual pump) blows</td>
<td>32652000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Description</td>
<td>Details</td>
<td>Code</td>
<td>Level</td>
<td>Category</td>
<td>Applicable</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Reusable pneumatically-powered ENT applicator</strong></td>
<td>An applicator used to administer a powdered drug into the ear, nose or throat (ENT) by blowing the air. This device is reusable.</td>
<td>33466000</td>
<td>1</td>
<td></td>
<td>5-①</td>
</tr>
<tr>
<td><strong>Breathing gas mixer</strong></td>
<td>A device used to spray aerosolized liquid drugs into the air that the patient inhales. Usually, manually operated. Different from nebulizers, it does not have a baffle, and the particle size of aerosols is not homogenous.</td>
<td>36327009</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>ENT drug solution spray</strong></td>
<td>A sprayer with a hand-held valve (manual pump) that blows the drug into the ear, nose or throat (ENT).</td>
<td>70453000</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>Diagnostic nebulizer</strong></td>
<td>A device used for asthma assessment. It generates cold air (–10°C to –20°C), and the patient inhales this air via a mouth piece to induce an asthma attack. The severity of respiratory tract occlusion is assessed so that the attending physician can prescribe appropriate treatment</td>
<td>37072000</td>
<td>1</td>
<td></td>
<td>5-①</td>
</tr>
<tr>
<td><strong>Pleural drainage system</strong></td>
<td>A plastic device that consists of 1 or 2 chambers connected to an aspiration tube. Connected to a thoracic cavity drain to eliminate blood, air, and purulent discharge from the thoracic cavity.</td>
<td>10817000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Suction system operated by gas</strong></td>
<td>A device that generates negative pressure used for such treatment as the aspiration of liquid or granular substances. Operated by compressed gas (air or oxygen) fed via a nozzle. Usually used at the bedside, in an operating room, and anesthesia room.</td>
<td>36607000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Suction system operated by vacuum</strong></td>
<td>A device used for such treatment as the aspiration of liquid or granular substances by using negative pressure supplied by the hospital's medical gas supply system. Usually used at bedside, or in an operating room.</td>
<td>36778000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Reusable ear catheter</strong></td>
<td>A tubal surgical device made of rigid plastic or metal. Inserted into the ear canal, and used to secure a passage for aspiration, perfusion, and the insertion of surgical devices. This device is reusable after cleaning and sterilization.</td>
<td>33395000</td>
<td>1</td>
<td></td>
<td>5-①</td>
</tr>
<tr>
<td><strong>Canister for suction system</strong></td>
<td>A canister used with an aspirator to collect body fluids. This device is for single-use. Usually made of plastic, stored as folded individually in a package, and assembled before use. Some are provided as a finished canister. Dispose of it in accordance with the applicable local environment laws and regulations. Some have a non-return valve that prevents contamination.</td>
<td>34858000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Reusable suction unit bottle</strong></td>
<td>A glass or plastic bottle used with an aspirator to collect body fluids. It forms an airtight seal using a top or a lid. This device is reusable.</td>
<td>38476000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Reusable general-purpose suction tip</strong></td>
<td>A tool connected to an aspirator to adjust or indicate the aspiration for surgery or treatment. This is a reusable aspiration tip for general-purpose.</td>
<td>38749000</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Powered douche</strong></td>
<td>A device that squirts liquid into a body part. Used to maintain hygiene or for treatment. Electrically operated.</td>
<td>34628000</td>
<td>1</td>
<td></td>
<td>2,12</td>
</tr>
<tr>
<td><strong>Sterile manually-operated douche</strong></td>
<td>A device that squirts liquid into a body part. Used to maintain hygiene or treatment. Uses sterilized liquid and is operated manually.</td>
<td>34629000</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

324/387
<table>
<thead>
<tr>
<th>Device Type</th>
<th>Description</th>
<th>Code</th>
<th>Class</th>
<th>Age</th>
<th>Applicable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manually-operated douche</td>
<td>A device that squirts liquid into a body part. Used to maintain hygiene or for treatment. Operated manually.</td>
<td>34630000</td>
<td>1</td>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Needle douche</td>
<td>A needle without a blade point. Used to clean inside the oral cavity, dental pulp cavity, and root canal, remove fragments, suction and wash off foreign substance or contamination during surgery, and suction a drug solution.</td>
<td>70459000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>–</td>
</tr>
<tr>
<td>Urological irrigation system</td>
<td>A device used to infuse water for washing into the urinary tract via a nozzle inserted into the urinary tract. It consists of a liquid container connected to the nozzle via a tube, and components that control the water pressure released from the nozzle, temperature and flow rate.</td>
<td>43415000</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Colonic irrigation system</td>
<td>A device used to infuse water into the large intestine via a nozzle inserted into the rectum to expel the contents of the lower section of the large intestine. It consists of a liquid container connected to the nozzle via a tube, and components that control the water pressure released from the nozzle, temperature and flow rate. Some have accessories used for connection to a console type toilet bowl, water pipe and sewage pipe.</td>
<td>43827000</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Temporary use bladder irrigation kit</td>
<td>A package for temporary use that contains injection syringes and other components used for cleaning the urinary bladder.</td>
<td>10406001</td>
<td>1</td>
<td>2,5</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Ear irrigation kit</td>
<td>A package that contains injection syringes and other components used for cleaning the ear canal.</td>
<td>11371000</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Oral lavage unit</td>
<td>A dental device specifically designed for dental treatment. Used to wash the site to be treated (e.g., cavity, carious cavity) to ensure cleanliness and remove tooth fragments, remaining filler, necrotic cell debris and infectious agents. It basically utilizes the...</td>
<td>12304019</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental oral lavage unit</td>
<td>A dental device specifically designed for dental treatment. Used to wash the site to be treated (e.g., cavity, carious cavity) to ensure cleanliness and remove tooth fragments, remaining filler, necrotic cell debris and infectious agents. Connected to an active medical device.</td>
<td>12304020</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Powered dental oral lavage unit</td>
<td>An apparatus comprising a syringe that is connected to a compressor and which squirts saline solution by air pressure from a handpiece to wash the affected site after oral surgery. Some are connected to a small gas cylinder.</td>
<td>12304030</td>
<td>1</td>
<td>2,5</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Reusable dental syringe</td>
<td>A invasive, dental devices used to wash the inside of the oral cavity, dental pulp cavity and root canal, and remove foreign substances and cutting debris. Active devices and instruments connected to an active device are excluded. This device is reusable.</td>
<td>35970021</td>
<td>1</td>
<td>2,6</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Perineal irrigation kit</td>
<td>A package that consists of injection syringes and other items used for cleaning the perineum.</td>
<td>12996000</td>
<td>1</td>
<td>2,5</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Wound irrigation kit</td>
<td>A package that consists of injection syringes and other items used for cleaning the wound.</td>
<td>14462000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Item Description</td>
<td>Definition</td>
<td>Code</td>
<td>Category</td>
<td>Type</td>
<td>Applicability</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
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<td>-------</td>
</tr>
<tr>
<td>Ear irrigation syringe</td>
<td>A syringe with a plunger used to flush perfusate into the ear canal.</td>
<td>35025000</td>
<td>I</td>
<td>2,5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT lavage unit</td>
<td>A device specifically designed to clean the treatment site in order to remove necrotic cell debris, infectious agents or foreign materials in ear, nose and throat (ENT) treatment. Usually, it is operated by the pulsatile flow of sterilized water such as physiological saline used to cleaning the treatment site.</td>
<td>35152000</td>
<td>I</td>
<td>2,5-1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Nose applicator</td>
<td>A device used to directly administer a drug into the nasal cavity. It consists of a horn-like cup and holder. The device is inserted into the nasal cavity, and filled with warm salt water or other treatment solution for washing and treating the nasal passages and mucosa.</td>
<td>41599000</td>
<td>I</td>
<td>2,5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Disinfectant injector</td>
<td>A device used to inject disinfectant.</td>
<td>70462000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Cleaning agent injector</td>
<td>A device used to inject a cleaning agent.</td>
<td>70463000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Powered dental douche</td>
<td>A device used to squirt saline solution using air pressure from a small gas cylinder or compressor for cleaning the affected site after oral surgery.</td>
<td>70464000</td>
<td>I</td>
<td>2,5-1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Endoscopic irrigation/aspiration unit</td>
<td>A perfusion/aspiration device for perfusion/aspiration (for washing) with liquid for better endoscopic observation in a body cavity or lumen. Used with an endoscope. It is sterilized.</td>
<td>70465000</td>
<td>I</td>
<td>2,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Utensil decontamination washer</td>
<td>A washer used for (chemical or heating) decontamination/disinfection of reusable surgical devices, anesthetic tools, shoes, and other surgical tools. Some have a built-in drier.</td>
<td>35424000</td>
<td>I</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Powered endoscope lens cleaner</td>
<td>A device that supplies liquid or gas to the end surface of the lens to eliminate blood and foreign materials adhering to the lens. A metal or plastic sheath is attached to the endoscope before use. The device that supplies liquid or gas is electrically operated.</td>
<td>70466000</td>
<td>I</td>
<td>2,12</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Douche kit</td>
<td>A kit containing items used with the washer unit for washing a specific site or part of the patient/operator.</td>
<td>11297001</td>
<td>I</td>
<td>2,12</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Bone particle collector</td>
<td>A container used to collect bone fragments generated by sawing, reaming, perforation, and rasping in orthopedic surgery. It is not good to leave bone fragments in the joint region because the fragments could cause osteohypertrophy and the joint cannot move after the operation.</td>
<td>17131000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Delivery</td>
<td>Installation</td>
<td>Remarks</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Powered pinch valve</td>
<td>A device that is used to support for body cleaning that closes and opens the cleaning tube with an electrically operated pinch valve, and releases and stops the supply of cleaning solution that flows down from the cleaning solution bag by gravity.</td>
<td>70467000</td>
<td>1</td>
<td>2,12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Irrigation/aspiration volume measuring unit</td>
<td>A device that measures the balance (between the volume released from the cleaning pump and the volume collected into the collection bottle) of the volume (weight) of a cleaning solution that is released from an electrically operated body washer, and collected by the aspiration device.</td>
<td>70468000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthopedic operation table</td>
<td>An adjustable table equipped with an elevatable top that supports the patient’s body, and special device that assists and performs the traction of the patient’s limbs for orthopedic procedures on an upper or lower limb. The special functions of this device enable the</td>
<td>35394000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Gynaecological operation table</td>
<td>A surgical table used for gynecological surgery.</td>
<td>36618000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>General-purpose manually-operated operation table</td>
<td>A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Manual or hydraulic operation.</td>
<td>36867010</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Operation table accessories</td>
<td>Accessories that come with the surgical table.</td>
<td>70469000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Column operation table system</td>
<td>A permanent or semi-permanent column installed in an operating room, and used to introduce and install a removable tabletop (brought in by a compatible trolley).</td>
<td>36611000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Battery-powered mobile operation table system</td>
<td>A semi-permanent tabletop column installed in an operating room and used to introduce and install a removable tabletop which carries the patient when preparing for surgery. This can be moved around the operating room to allow the operator to perform all types of surgery smoothly. It is battery-operated, and has no permanent electrical connection. The battery should be charged by the main power supply. The tabletop should be transformed from the column with a compatible trolley by the staff.</td>
<td>44145000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>–</td>
</tr>
<tr>
<td>Powered general-purpose operation table</td>
<td>A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Electrically line or battery operated.</td>
<td>36867020</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic operation table</td>
<td>A device specifically designed to support the patient’s body in ophthalmic surgery. Proper support and fixation of the patient’s body allows the surgeon to adopt the optimal approach. A narrow table top allows the surgeon to reach the center line. This is not suitable for general surgery.</td>
<td>37225000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Operation table system</td>
<td>A system that consists of several components that form a complete surgical table system. It is used to replace tabletops, change the patient’s position, and transfer the patient to and from the operating room. Usually, it consists of columns, a removable tabletop, remote controller for the trolley, and a trolley.</td>
<td>37325000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Delivery table</td>
<td>An adjustable table for examination/treatment. Used to support the female patient’s body in an appropriate position for labor, delivery, and other pregnancy-related examination/treatment. Usually, it is equipped with leg holders, handles, a container for the placenta, and other items.</td>
<td>13960000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Table Type</td>
<td>Description</td>
<td>Code</td>
<td>Delivery</td>
<td>Position</td>
<td>Others</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<td>----------</td>
<td>----------</td>
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<td></td>
</tr>
<tr>
<td>Urological table</td>
<td>An adjustable table for examination/treatment equipped with an appropriate (e.g., metal, plastic) table top supported by a fixed base. It has a knee clutch and handle. Operated manually or by electrical control for lowering/raising and tilting using a machine.</td>
<td>13969000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Birthing bed</td>
<td>A bed designed for the use during labor and delivery. Accessories can be attached to the bed.</td>
<td>15732000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Gynaecological examination/treatment table</td>
<td>An adjustable table for examination/treatment. Used to support the female patient's body in an appropriate position for gynecological examination/treatment.</td>
<td>36065000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Proctological table</td>
<td>An adjustable table for examination/treatment. Usually, equipped with knee/elbow holders and heel stirrups. Used to support the patient's body in an appropriate position that the patient's back is exposed during perianal examination/treatment.</td>
<td>36165000</td>
<td>1</td>
<td>1,12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Brachytherapy template</td>
<td>A template used to guide the direction of insertion of a puncture needle when inserting the radiation source next to the tumor guided by ultrasound.</td>
<td>70470000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>General-purpose diagnosis/treatment table</td>
<td>A table for general diagnosis and procedures. This may be suitable for performing several basic functions (e.g., lifting up and down or tilting the patient). Used in examination and operating rooms. This does exclude tables that fall under &quot;general examination/treatment table.</td>
<td>13958009</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>General-purpose examination/treatment table</td>
<td>A table for general examination/treatment. Some are equipped with several basic functions (e.g., lowering/raising, tilting). Used in examination and operating rooms. Electrically or manually operated.</td>
<td>13958000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Ophthalmic examination/treatment chair</td>
<td>A chair used for ophthalmic examinations, treatment or surgery. The chair facilitates such postures as sitting, semi-sitting, or semi-recumbency that allow easy access to the patient and comfort for the patient. The chair can be lifted up and down. Some are stand-alone, others are connected to a diagnostic table unit.</td>
<td>15723000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Asphyxia treatment table</td>
<td>A table equipped with an aspirator, oxygen supply device, heater (e.g., infrared lamp on the top, or infant warmer pad at the bottom). Used for resuscitation of a neonate who cannot breathe spontaneously at birth and is in a hypoxic state.</td>
<td>36685000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Physical therapy table</td>
<td>A table for examination/treatment that is equipped with foot support, and the height and position are adjustable (e.g., vertical tilt from recumbent to upright position). Some are equipped with exercise training devices (e.g., pulley, turntable) and other accessories (e.g., cervical vertebral bar, arm suspenders). Used to improve the blood circulation of the lower extremities of patients with neurological diseases (e.g., spinal cord injury), assist muscle tone, and improve mobility.</td>
<td>13964000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Rotating vestibulo-ocular function chair</td>
<td>By assessing the deviation of optical response to rhythm exercise (nystagmus) by angular acceleration or angular deceleration or stimulation to the vestibular system, the vestibular system can be assessed.</td>
<td>17217000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Examination/treatment chair</td>
<td>A chair operated manually or electrically, and used for blood collection and dialysis. Also used for transferring the patient.</td>
<td>16437000</td>
<td>1</td>
<td>1,12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-powered dental examination/treatment chair</td>
<td>A chair for examination that supports the patient at the desired position for specific dental treatment and examination. This exclude electrically operated one. The height and angle of the back rest are adjustable, and the chair can be tilted with the body axis as the axis of rotation.</td>
<td>34935020</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical light system</td>
<td>An illuminator that consists of 2 or more light heads individually installed on rotary arms. Some have light heads of the same size and others have different sizes. Some have a combination of operating room illuminator and examination room illuminator. Some have a mount to install a camera or other device.</td>
<td>37332000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Operating light</td>
<td>A operating light that illuminates the surgical site for a long period for the optimal visualization of small objects with low contrast at various depths or in small incisions. This reduces shadows and minimizes the misperception of colors. Usually, the light source at the lamp head sheds light. The light source is a valve that reflects the light with light.</td>
<td>12282000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td>applicable</td>
</tr>
<tr>
<td>Examination light</td>
<td>An illuminator used for medical consultation and treatment. Installed on the ceiling or wall. Some serve as a part of the illumination system that consists of several light heads.</td>
<td>12276000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmodiaphanoscope</td>
<td>An ophthalmic device used to examine the back surface of the eye (retina) via oral vestibule by transillumination.</td>
<td>12804000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Device</strong></td>
<td><strong>Description</strong></td>
<td><strong>MHL</strong></td>
<td><strong>Class</strong></td>
<td><strong>Status</strong></td>
<td><strong>Remarks</strong></td>
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</tr>
<tr>
<td>Entoptoscope</td>
<td>An ophthalmic device used to examine the light transmitting parts of the eye.</td>
<td>15288000</td>
<td>I</td>
<td>12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Mobile examination light</td>
<td>An illuminator that has all the characteristics of the medical illuminators. Most of them are equipped with a pantograph-type counter balance assembly. Usually used for medical consultation and treatment of minor diseases. It is designed to allow easy movement from one place to another.</td>
<td>36843000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Head worn light</td>
<td>An apparatus (lamp) designed to be attached to the head of the operator. The lamp is attached to a band or helmet frame so that it is placed on the forehead of the operator, and directly illuminates the visual field during surgery, diagnosis, or treatment. Usually, it consists of a magnifying lens, reflector, and a component connected to an optical fiber cable (to transmit cold light or supply electric power from a battery pack).</td>
<td>11963000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>General/plastic surgery mirror</td>
<td>A device that displays the virtual image of an object placed in front of it. Used to assist the surgeon during general surgery and plastic surgery.</td>
<td>32261000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic mirror</td>
<td>An ophthalmic device with a mirror that reflects the beam during examination of the eyes and associated structures. Some have a round or concave mirror attached to the headband.</td>
<td>32707000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT mirror</td>
<td>The mirror has the surface sufficiently polished so as to form the virtual image of an object placed in front of it by reflecting non-diffusing light. Used for medical treatment of the ear, nose and throat (ENT). A thin handle is attached to the opposite side of the headband.</td>
<td>33431000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT headband mirror</td>
<td>A device with a round concave mirror on the headband so as to project luminous flux into the nasal cavity or throat during clinical examination.</td>
<td>34637000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>General-purpose light source</td>
<td>An apparatus that generates intense light (known as cold light) used for general surgery or medical treatment. The light is transmitted to the treatment apparatus (e.g., headlight, microscope, and endoscope) directly or more usually via an optical fiber cable.</td>
<td>32037000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Fibreoptic operating light with/without Illuminator</td>
<td>A operating light that illuminates the surgical site for a long time in order to optimally visualize small objects with low contrast from small incisions of various depths. Usually, it functions with the light supplied from the light source outside the surgical site via the optical fiber tube bundle. Installed on the ceiling or an appropriate floor device.</td>
<td>32241000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Transilluminator light</td>
<td>A lamp equipped with an intense light source. It illuminates the skin and soft tissue to make it semitransparent for examination, and for direct observation of soft tissue (e.g., content of the breast or penis) by a healthcare professional.</td>
<td>36761000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Ear light</strong></td>
<td>An apparatus that illuminates the auditory canal to confirm the position of a plug inserted into the auditory canal in order to restrict the passage of the ear impression material.</td>
<td>41238000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Alcohol disinfector</strong></td>
<td>An apparatus that sprays alcohol mist which is a disinfectant to inactivate microorganisms, and disinfect and sterilize the patient’s bed, Japanese bedding (Futon), and mattress.</td>
<td>70474000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Hot water pasteurization device</strong></td>
<td>A warming bath that is usually small, and heats water to 70-75°C for at least 20 minutes, and kills almost all infectants. This method is indicated only for the cases that do not need complete sterilization.</td>
<td>44555000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Peritoneal perfusate thermal conditoner</strong></td>
<td>An apparatus for storage at a constant temperature. This is used for heating and storage of perfusate before infusion.</td>
<td>70478001</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td><strong>Nursing bottle incubator</strong></td>
<td>A device to keep feeding bottles warm.</td>
<td>70479000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td><strong>Human tissue incubator</strong></td>
<td>An apparatus for human tissue cultivation that maintains a stable, appropriate environment where oxygen does not exist.</td>
<td>70481000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Cardiac valve prosthesis sizer</strong></td>
<td>A surgical device manually operated during heart valve replacement. It measures the size of an orifice used for implantation of an artificial heart valve.</td>
<td>17703010</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td><strong>Annuloplasty ring sizer</strong></td>
<td>A surgical device manually operated during valvuloplasty. It measures the size of orifice used for implantation of a valvuloplasty ring in an appropriate size. It includes handles used for the sizer and holder.</td>
<td>17703020</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td><strong>Valve prosthesis tester</strong></td>
<td>A surgical device manually operated during heart valve replacement. Used to confirm the mobility of the artificial valve lobes.</td>
<td>70482000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td><strong>Valve prosthesis holder and handle</strong></td>
<td>A surgical device manually operated during heart valve replacement. Used to hold the artificial valve or change the direction of the artificial valve.</td>
<td>70483000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
<td>—</td>
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<tr>
<td>Device Description</td>
<td>Description</td>
<td>Tariff Number</td>
<td>Code</td>
<td>Country</td>
<td>Applicability</td>
<td>Notes</td>
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<tr>
<td>Measuring device for vascular graft</td>
<td>A surgical device that measures the patient's vascular diameter in order to select an appropriately sized artificial vascular graft to be used for blood vessel prosthesis implantation or nerve regeneration inducing material placement.</td>
<td>70490000</td>
<td>I</td>
<td>N/A</td>
<td>5-1</td>
<td>—</td>
</tr>
<tr>
<td>Orthopaedic bone cement mixer</td>
<td>A device that kneads or mixes (bone) cement or an artificial bone implant used for orthopaedic surgery. It includes a mixing spatula, deaeration tube, and other accessory devices. This device is for single-use.</td>
<td>33191000</td>
<td>I</td>
<td>N/A</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Reusable powered orthopaedic cement mixer</td>
<td>An electric device used to mix polymethyl methacrylate powder and methyl methacrylate monomer to produce polymer bone cement. Usually, it includes a bowl with an electric spatula (a mixing device made of wire). Connected to a vacuum fume exhauster. This device is reusable after proper cleaning and sterilization.</td>
<td>42982000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Bone cement deaeration tube</td>
<td>A tube that is used to remove the gas generated when using bone cement.</td>
<td>70507000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Dialysis set holder</td>
<td>A device that is used to hold and fix a dialysis set when dialysis is performed.</td>
<td>32144000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Breaker for blood tubing</td>
<td>A device that shuts off the extracorporeal hemodialysis circuit in the event of an emergency.</td>
<td>70548000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td>—</td>
</tr>
<tr>
<td>Shunt adaptor</td>
<td>An adaptor (usually, a small part) that is used for connecting the tubes to shunts for hemodialysis or other purposes. It enables those items to be used in combination by making them mutually compatible. This device is for single-use.</td>
<td>35338000</td>
<td>I</td>
<td>2</td>
<td>applicable</td>
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</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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<tr>
<td>Ventilator filter</td>
<td>A sieve used to prevent particles and microorganisms from entering the gas line of a artificial respirator. The filter is made of paper, fiber or copper strips, and is usually installed in a plastic container.</td>
<td>14352000</td>
<td></td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td>Breathing gas mixer</td>
<td>An apparatus that adjusts several different types of medical gases supplied to a patient in order to maintain them at a constant concentration.</td>
<td>70563000</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilator mask</td>
<td>A mask that is connected to the respiratory circuit of an artificial respirator, covers the patient’s nose and mouth, and supplies gases from the artificial respirator. Some are a mouthpiece type.</td>
<td>70564000</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilator pressure monitor</td>
<td>A monitor that measures the pressure of an artificial respirator circuit during treatment or diagnosis. Some are the latest electronic measurement devices, and other are simple mechanical devices.</td>
<td>70565000</td>
<td></td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable general-purpose water trap</td>
<td>A water trap that is used inside a circuit or connected to the circuit, when highly humid gas or air passes through the circuit (respirator), condensation forms rapidly. It eliminates the accumulated liquid periodically, and drains it without interrupting the treatment.</td>
<td>31286000</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use ventilator water trap</td>
<td>A water trap used for the respiratory circuit of an artificial respirator. It collects condensation accumulated during heating or humidifying. Usually, it uses a 22 mm tapered connector, and is connected to the exhalation rim of a respiratory circuit. In order to prevent liquid leakage when disconnecting it from the circuit, some are equipped with an automatic sealing function. This device is reusable after proper cleaning by each use.</td>
<td>36276000</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable ventilator water trap</td>
<td>A water trap used for the respiratory circuit of an artificial respirator. It collects condensation accumulated during heating or humidifying. Usually, it uses a 22 mm tapered connector, and is connected to the exhalation rim of a respiratory circuit. In order to prevent liquid leakage when disconnecting it from the circuit, some are equipped with an automatic sealing function. This device is reusable after proper cleaning by each use.</td>
<td>36277000</td>
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<td>1,12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-use general-purpose water trap</td>
<td>A water trap that is used inside a circuit or connected to the circuit, when highly humid gas or air passes through the circuit (respirator), condensation forms rapidly. It eliminates the accumulated liquid periodically, and drains it without interrupting the treatment or procedure. Usually, a standard tapered connector is used. This device is reusable after proper cleaning by each use.</td>
<td>41679000</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gas extraction tubing</td>
<td>A hollow cylindrical device used to extract unnecessary gases from the source of an anesthesia apparatus or system under its control. Used to protect the work environment from contamination. Usually, the inner diameter is larger than that of the tube of the compressed gas. The tube has low resistance to the extraction process, and connects the gas extraction apparatus to the duct system at the hospital or facility. Some are a color-coded polymer tube which is reinforced with woven polyester.</td>
<td>16821000</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen tent</td>
<td>A flexible tent installed on the upper side of the bed or around the head of the patient in order to increase the oxygen tension. Some use humidification and temperature control. Designed for patients who cannot tolerate a nasal prong or face mask.</td>
<td>12893000</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topical oxygen therapy sleeve</td>
<td>A flexible sheath used to apply an oxygen-enriched gas to the skin. The sleeve covers the hand or the leg, or the lower part of the body below the head.</td>
<td>13620000</td>
<td></td>
<td>2</td>
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</tr>
<tr>
<td>Mist tent</td>
<td>A canopy that is hung on the patient's bed or a mask that is placed on the patient's chin for aerosol drug therapy. Some are used in a highly humid environment or for oxygen therapy. This technique can free the patient free from direct contact with a nasal cannula.</td>
<td>12554000</td>
<td></td>
<td>2</td>
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</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Applicable</td>
<td>Notes</td>
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</tr>
<tr>
<td>Oxygen gas analyser</td>
<td>An apparatus that measures the oxygen concentration of a gas or liquid (blood) by paramagnetism, mass spectrometry, polarography, thermal conductivity, or gas chromatography.</td>
<td>35219000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Air and oxygen mixer</td>
<td>An apparatus that mixes oxygen and air, selects the arbitrary oxygen concentration (21-100%), and supplies it to the peripheral respiration assisting apparatus such as an artificial respirator and oxygen tent.</td>
<td>70578000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>High-pressure gas regulator</td>
<td>A pressure reducing valve that decreases the pressure to a low constant operation pressure. The valves for medical gas pipeline systems (JIST7101) are excluded. This is a 1-step or 2-step regulator. It comes as both a piston type and diaphragm type. This should be high pressure gas regulator devices.</td>
<td>35300000</td>
<td>I</td>
<td>2</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Radiant heat shield hood</td>
<td>A hood used to cover a baby in an infant incubator who cannot maintain body temperature in equilibrium due to the loss of radiant heat, and prevent the loss of radiant heat.</td>
<td>70584000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Defibrillation body surface electrode</td>
<td>A conductor used to transmit a controlled electrical shock from a defibrillator to the patient in order to restore normal heartbeat. A cable set includes electrodes to be connected to the defibrillator. Used on the chest which is not opened (normal). (Usually, patient's heart is fibrillating.) Some may have physical sensors to measure chest.</td>
<td>15033001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Peritoneal dialysis circuit welder</td>
<td>An apparatus that automatically connects thermoplastic tubes aseptically used for peritoneal dialysis hemodialysis. The tubes to be connected are laid in parallel, and cut with a heated blade. The cut sections are pressed together without contacting the external air, and the heated blade is removed. This procedure prevents contamination with.</td>
<td>70587000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>One-piece urostomy bag</td>
<td>A plastic bag used as a urine collector for urinary tract control. It is temporarily invasive via the stoma.</td>
<td>31068009</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Multiple-piece urostomy bag</td>
<td>It consists of two or more plastic bags attached to the skin as a urine collector for urinary tract control. It is temporarily invasive via the stoma. It is equipped with a non-return valve that prevents the urine from remaining at the bottom of the stoma, and a drain tap to allow the urine to be discharged.</td>
<td>31069009</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable manually-operated radioactive source placement auxiliary device</td>
<td>A manually operated brachytherapy assisting auxiliary device designed for radiotherapy that does not specify treatment site. A single or module device designed to assist the manual, percutaneous placement of single or multiple radiation sources for treatment, which is performed by using an applicator resembling a puncture needle (hollow needle), to the treatment site. Some have a standard configuration, and other are designed to accept specific radiation sources. Used with various applicators such as a hollow needle.</td>
<td>70601000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Non-powered X-rays radiation therapy table</td>
<td>A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus. The height and position of the tabletop is adjusted by electronic or software control. Either fixed or mobile. Some are integrated with an X-ray therapy system.</td>
<td>40682000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Powered X-rays radiation therapy table</td>
<td>A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus. The height and position of the tabletop is adjusted by electronic or software control. Either fixed or mobile. Some are integrated with an X-ray therapy system.</td>
<td>40683000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-powered remote irradiation therapy table</td>
<td>A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning and table height control. Either fixed or mobile. Some are integrated with an X-ray therapy system.</td>
<td>40684000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Powered remote irradiation therapy table</td>
<td>A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus. The</td>
<td>40685000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Table Title</th>
<th>Description</th>
<th>Code</th>
<th>Combination</th>
<th>Applicable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-powered accelerator system table</td>
<td>A mechanically-operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses a medical linear accelerator or non-linear accelerator. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and the height and position of the tabletop is adjusted by electronic control. The height and position of the tabletop is adjusted by electronic control.</td>
<td>40686000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered patient table for accelerator</td>
<td>A bed operate by programmable for electric radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses medical linear accelerator or non-linear accelerator. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and the height and position of the tabletop is adjusted by electronic control.</td>
<td>40687000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-powered neutron therapy table</td>
<td>A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from a nuclear reactor, etc. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and the height and position of the tabletop is adjusted by electronic control.</td>
<td>40690000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered neutron therapy table</td>
<td>A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from the nuclear reactor, etc. In order to prevent or eliminate an accidental activation during treatment, the bed is made of hydrogenic materials with low molecular weight. The height and position of the tabletop is adjusted by electronic or software control.</td>
<td>40691000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-powered radionuclide brachytherapy table</td>
<td>A programmable bed for electric radiotherapy to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and the height and position of the tabletop is adjusted by electronic or software control.</td>
<td>40692000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Powered radionuclide brachytherapy table</td>
<td>A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically. The height and position of the tabletop is adjusted by electronic or software control.</td>
<td>40693000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Accelerator system collimator electron applicator</td>
<td>The electron applicator is a collimator accessory of an accelerator for treatment. It is attached between the beam emission port of the accelerator's collimator housing and the subject. This is used as the final collimation before the electron beam reaches the subject. Placed near the skin, and used to decrease the amount of scattering of electrons that reach the target treatment site. The configuration of the conical part of these apparatuses is determined by the size and shape of the target treatment site.</td>
<td>42268000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Wet hot pack unit</td>
<td>An apparatus that stores a reusable hot pack in warm water or other appropriate medium at the desired temperature so it can be used whenever necessary.</td>
<td>38469000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Hot pack</td>
<td>A pack that contains a heating medium is warmed by a heating apparatus. The warmed pack is applied to the affected site as an antiphlogistic procedure (thermotherapy). Some are also used as a cooling pack after being chilled by a cooling apparatus. This device is reusable.</td>
<td>37240010</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Cold pack unit</td>
<td>An apparatus that cools the content of a reusable hot/cold pack before applying the pack (wet dressing). Usually, it can cool more than one pack at a time.</td>
<td>36034000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Cold pack</td>
<td>A pack used for an antiphlogistic procedure (cryotherapy). A pack that contains a cooling medium is chilled by a cooling apparatus, and applied to the affected site.</td>
<td>37240020</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Elastic stocking</td>
<td>Medical elastic stockings etc. (including elastic sleeves for arms) used for the purpose of promoting venous return, such as alleviation or prevention of the venous blood and lymph fluid in the extremities. It has a function to gradually apply compression from the head to the extremities and back muscles.</td>
<td>31724000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-active extension/traction rotary motion equipment</td>
<td>A non-active apparatus for training, enhancement, and rehabilitation. It is used to strengthen, sustain, develop or restore the muscle strength of the upper and lower extremities and back muscles.</td>
<td>70610000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-active automatic traction unit</td>
<td>A non-active apparatus with a harness which is worn on the head or the pelvis, and used to stretch a part of body (e.g., cervical spine, vertebral). Usually, it consists of a control unit.</td>
<td>14105001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Non-active automatic intermittent traction unit</td>
<td>A non-active apparatus for traction therapy. Designed to intensify or release a force either in an intermittent or cyclic mode according to the pre-selected minimum/maximum levels and duration.</td>
<td>14106001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Applicable</td>
<td>N/A</td>
<td></td>
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<tr>
<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Non-active simplified traction unit (e.g., head halter, pelvis belt, traction splint or harness, beam structure) that generate the traction force without any motion (stationary)</td>
<td>35519001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-powered exercising equipment with measuring functions</td>
<td>70612000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-active hand passive motion exerciser</td>
<td>17137001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-active leg passive motion exerciser</td>
<td>35977001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-active upper limb passive motion exerciser</td>
<td>35978001</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Non-active respiratory exerciser</td>
<td>11634001</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable acupuncture needle</td>
<td>35207001</td>
<td>I</td>
<td>6</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Reusable non-active contact needle</td>
<td>70613001</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Venous return circulatory assist system</td>
<td>10849000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Skin abrasion unit</td>
<td>11177000</td>
<td>I</td>
<td>12</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Impactor</td>
<td>32856000</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Hemostasis pressure device</td>
<td>70617000</td>
<td>I</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Binocular loupe</td>
<td>32692000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Surgical microscope</td>
<td>36354010</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transportable surgical microscope</td>
<td>36354020</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Microscope accessory</td>
<td>37294000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>Quantity</td>
<td>Unit</td>
<td>Applicable</td>
</tr>
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<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Frenzel glasses</td>
<td>Glasses used to observe the movement of a subject's eyeball. Some are equipped with a light, infrared light, or infrared CCD camera.</td>
<td>70653000</td>
<td>1</td>
<td>I</td>
<td>applicable</td>
</tr>
<tr>
<td>Mounted surgical microscope</td>
<td>A surgical microscope to be installed on the ceiling.</td>
<td>36354030</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Endoscope holder</td>
<td>A holder that supports and adjusts a laparoscope, or other endoscope, and surgical devices to a desired position during surgery. It consists of joints and rigid or semi-rigid arms. Some are equipped with such functions as braking, balancing, minute positioning, and position detection.</td>
<td>16240000</td>
<td>1</td>
<td>I</td>
<td>applicable</td>
</tr>
<tr>
<td>Electrosurgery electrode holder</td>
<td>A holder that temporarily holds a hand control, electric surgical electrode (pencil electrode) which is activated, but not used during surgery.</td>
<td>35043000</td>
<td>1</td>
<td>I</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use electrode cleaner</td>
<td>A single-use cleaner that is used to eliminate carbides that have accumulated on the surface of an active electrode after use.</td>
<td>70654000</td>
<td>1</td>
<td>I</td>
<td>N/A</td>
</tr>
<tr>
<td>Cable or switch for electrosurgical unit</td>
<td>Cables, switches or adaptors used to transmit signals, supply electric power, for extending the connection between an electric surgical device and the apparatuses connected to them for control. This category does exclude extensions connected to the primary power source.</td>
<td>70657000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Connection cable or switch for ablation device</td>
<td>Cables, switches or adaptors used to transmit signals, supply electric power, for extending the connection between the medical device used as a probe and the apparatuses connected to them for control, during atheroablation angioplasty or other procedures. This category does exclude to use as extensions connected to the primary power source.</td>
<td>70658000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable tourniquet</td>
<td>A hand-like device applied to the extremities (arm or leg) so as to inhibit circulation, and block the normal blood flow to and from the distal part. Used with a tourniquet that adjusts the pressure. The cuff usually consists of two parts, and can change the site to which it is applied.</td>
<td>17230000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Hemostatic unit</td>
<td>An unit transmits the air to the reusable tourniquet, select/control/maintain the tourniquet pressure during surgery.</td>
<td>70678000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental mirror</td>
<td>A dental device that usually consists of a mirror head and a handle, and is used for oral examination or retraction.</td>
<td>31776000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Periodontal pocket probe</td>
<td>A hand-held dental instrument used for measuring the depth of periodontal pocket in order to observe the severity of periodontal diseases.</td>
<td>31848000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental explorer</td>
<td>A hand-held device (probe) used for palpation in dental treatment. The tapered working part of the shaft comes in a needle, hook, or blunt configuration according to the purpose of use.</td>
<td>35812000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental gingival applicator</td>
<td>A dental instrument used to apply a plaster in the periodontal pocket.</td>
<td>70679000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental rubber dam clamp</td>
<td>A dental device with a buccal and lingual wing, or flange, used to anchor a rubber dam down to the cervical region of an exposed tooth. It is also used to retain a simple vapor barrier.</td>
<td>15712000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental rubber dam frame</td>
<td>A flexible frame that holds the expanded rubber dam for easy access to the surgical site.</td>
<td>31849000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Instrument Type</td>
<td>Description</td>
<td>Code</td>
<td>UCI</td>
<td>UCC</td>
<td>Unproc</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Dental rubber dam punch</td>
<td>A hand-held dental instrument used to open holes of various sizes on the rubber dam.</td>
<td>35553000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental rubber dam clamp forceps</td>
<td>A hand-held dental instrument used to apply and remove the rubber dam clamp.</td>
<td>35851000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental amalgam filling instrument</td>
<td>A hand-held dental filling instrument used to fill amalgam. The end is either flat or has saw-like configuration. The entire device is either straight or curved.</td>
<td>16460000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental amalgam carrier</td>
<td>A dental instrument specifically designed to be used for collecting and carrying the plastic amalgam, and packing it into a prepared cavity (cavity which has been formed).</td>
<td>35696000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental burnisher</td>
<td>A rotary dental device that has a working tip with a smooth or rippled surface. To achieve the glossy, smooth metal surface, it spreads and forms the cold work material or the corners of the cavity into a thin edge. It is also used to polish the surface of metallic.</td>
<td>35785000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental amalgam carver</td>
<td>A dental instrument used to create the anatomical form of the dental restorations for complete finishing. Used to give the amalgam a smooth finish.</td>
<td>35793000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental wax carver</td>
<td>A dental instrument used to carve the wax patterns. Usually, it has a dull blade edge in various sizes and shapes. It can be heated so as to soften the wax when forming the wax pattern.</td>
<td>35794000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental filling/restorative material applicator</td>
<td>A dental instrument used to apply the filler or restorative material in the oral cavity. It excludes reusable devices that come into direct contact with fillers and devices operated by an external energy source.</td>
<td>38782000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental plastic filling carver</td>
<td>A dental instrument with a blade or a nail used for severing, scraping or scratching the surface of plastic filler to form a smooth surface.</td>
<td>41861000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental automatic mallet</td>
<td>A hand-operated, spring-type device used to apply gold foil and inlay. The power is adjustable. A mallet used to remove prosthesis or foreign matter in oral cavity is included.</td>
<td>42395000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental filling instrument</td>
<td>A reusable hand-held dental filling instrument used to fill and apply dental materials such as dental cement, dental composite resin, dental core build-up materials, dental pit and fissure filler, dental cavity lining materials, dental pulp capping materials, and material for temporary dental sealing as well as dental drugs such as capping materials.</td>
<td>70680000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental compressed filling instrument</td>
<td>An instrument used for compressed filling of dental direct gold filler, gingival retraction cord, and dental periodontal dressing.</td>
<td>70681000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental mixing spatula</td>
<td>A spatula-shaped device used to knead or mix dental material (impression material, cement, etc).</td>
<td>38530000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental mixing instrument</td>
<td>A dental instrument used to knead or mix dental materials (e.g., impression materials, cement). Some are equipped with an injection function. Impression material kneading device and cement mixers are included. Spatula-like devices are excluded.</td>
<td>70682000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental curette</td>
<td>A dental instrument with a spoon-like working tip. Used for the tissue curettage.</td>
<td>31904000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Periodontic hoe</td>
<td>A hand-held dental instrument with a small blade that forms a right angle with the axis. It is operated by exerting a pulling motion.</td>
<td>31908000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
<td>Code</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Dental scaler</td>
<td>A hand-held dental instrument used to remove deposits such as tartar from the tooth surface for oral cleaning and periodontal treatment.</td>
<td>35320000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Periodontal curette</td>
<td>A dental instrument is usually a round shape, has a sharp blade with the surface ground into a concave shape, and has a half-round section view. Used for curettage of the periodontal pocket and root surface.</td>
<td>41660000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental excavator</td>
<td>A hand-held dental instrument with a curved blade to sever and remove carious dentin.</td>
<td>35811000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Tooth separator</td>
<td>A dental instrument used to move a tooth from the position where it is in contact with an adjacent tooth.</td>
<td>42340000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental rubber dam</td>
<td>A latex rubber sheet used to isolate the surgical field during dental treatment. After a hole is made in the sheet with a punch, the sheet is spread over the surgical site. Some are</td>
<td>11155010</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental rubber dam moisture barrier kit</td>
<td>A kit consists of a dental rubber dam, dental rubber dam clamp, dental rubber dam punch, and dental rubber dam frame. Used to prevent contamination with saliva and for damp proofing during dental treatment. (Consists of Class I items only.)</td>
<td>11155020</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental impression tray</td>
<td>When an impression is taken, the impression material is packed into the tray, which retains the material for pressure fitting.</td>
<td>16350000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental impression material syringe</td>
<td>This dental injection syringe is used to inject the impression material onto the impression tray.</td>
<td>35860000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental elevator/raspatory</td>
<td>A dental instrument is used to peel off tissues such as periosteum and mucosa, and remove prosthesis and foreign matter in the oral cavity during oral surgery. Electrical devices are excluded.</td>
<td>70683000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental elevator</td>
<td>A dental instrument with lever-like shape used to extract a tooth or remove a tooth root.</td>
<td>16480000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental carbide bur</td>
<td>A rotary cutting device has a working component made of tungsten carbide, is attached to the dental handpiece, and used to grind such hard tissues as teeth and bones. It can be also used to grind metal, plastic, porcelain, and other similar materials.</td>
<td>16668000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental steel bur</td>
<td>A rotary cutting device is made of carbon steel or stainless steel to grind such hard tissues as teeth and bones. It can be also used to grind metal, plastic, porcelain, and other similar materials used to produce dental workpieces</td>
<td>16669000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental diamond bur</td>
<td>A rotary cutting device has a steel working component coated with minute diamond crystals, is attached to a dental handpiece, and used to grind such hard tissues as teeth and bones. It can also be used to grind metal, plastic, porcelain, and other similar materials.</td>
<td>16670000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental plastic bur</td>
<td>A rotary cutting device has a plastic working component, is attached to a dental handpiece, and used to grind soft dentin in particular.</td>
<td>70684000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Item Description</td>
<td>Detailed Description</td>
<td>HS Code</td>
<td>Origin</td>
<td>Excise Duty</td>
<td>Contact Person</td>
</tr>
<tr>
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</tr>
<tr>
<td>Dental root canal reamer</td>
<td>A hand-held rotary dental instrument is used to wipe the wound of the root canal or to expand the root canal by performing a lateral cut.</td>
<td>31875001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Endodontic enlarger</td>
<td>A dental instrument is used to secure access to the root canal or to expand the root canal orifice.</td>
<td>31876000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental file rasp</td>
<td>A dental instrument has a working component that expands the root canal, and smooths the wall by severing or grinding when moved vertically.</td>
<td>31878011</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental file</td>
<td>A hand-held dental instrument expands the root canal, and smooths the wall of the root canal when reciprocally moved vertically, or lifted up.</td>
<td>31878021</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental endodontic rasp</td>
<td>A dental instrument for the root canal has a sharp protrusion on the working component. Used to grind and expand the root canal.</td>
<td>41878000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental broach</td>
<td>A dental instrument has a smooth working component at the end, and the round or polygonal section. Used to examine the root canal.</td>
<td>41865000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental endodontic applicator</td>
<td>A sharp-pointed dental instrument has a round cross section and a coarse working component at the end. Used to hold cotton or liquid when it is inserted into the root canal.</td>
<td>42334000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental cleanser</td>
<td>A long tapered dental severing instrument with a blade used to form/expand a hole in the root canal, or extract the pulp.</td>
<td>35784000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental drill</td>
<td>A dental instrument that is mainly used to open a hole in the cavity. Electrical devices are excluded.</td>
<td>70685000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental endodontic paste carrier</td>
<td>A hand-held rotary dental instrument has a working component equipped with a spiral or conical coil-like spring. Used to deliver filler or a drug to the root canal.</td>
<td>42336000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental root canal filling paste remover</td>
<td>A hand-held rotary dental instrument has a working component equipped with a spiral or conical coil-like spring, and is used to remove the filler from the root canal. Electrical devices are excluded.</td>
<td>70687000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental endodontic spreader</td>
<td>A dental instrument has a tapered working component, a round section view, and a sharp point. Used to pressure fit (mainly from the side) the filler into the root canal.</td>
<td>37678000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Endodontic plugger</td>
<td>A hand-held rotary dental instrument has a cylindrical or tapered working component, a round section view, and a flat point. Used to pack the filler into the root canal mainly in the direction of the axis.</td>
<td>41876000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental mandrels for rotary instruments</td>
<td>A shaft holds rotary dental severing devices such as a grindstone, grinding disk, circular saw, drill bit, lathe head stock, as well as disks, stones, and cups used for grinding.</td>
<td>35170000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental abrasive disk</td>
<td>A rotary dental instrument consists of a round flat sheet or slightly conical sheet that contains abrasive. It is fixed or made to be fixed to the mandrel in the center.</td>
<td>35807000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental engine and related instrument</td>
<td>An electric dental engine, engine stand, engine belt, engine bracket arm, and K4 pulley. Dental air-powered rotary unit and dental electrically-powered rotary unit are excluded.</td>
<td>70693000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Name</td>
<td>Description</td>
<td>Code</td>
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</tr>
<tr>
<td>Dental bite force analyser</td>
<td>This device measures the bite force (pressure) of the upper and lower teeth using an oral sensor without transmitting any energy to the human body. It detects abnormal distribution and imbalance of bite pressure due to neuromuscular function disorders such as sleep bruxism.</td>
<td>70699000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Occlusal contact analyser</td>
<td>This apparatus measures and analyzes the distribution, chronological order of the teeth contact using an oral sensor without transmitting any energy to the human body. It examines premature contact that could cause bite pressure imbalance and occlusal interference.</td>
<td>70700000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Gingival fluid measurer</td>
<td>This device measures the exudate from the gingival groove (groove between teeth and gum) to check for gingivitis.</td>
<td>33203000</td>
<td>I</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental temporomandibular joint sound-noise analyser</td>
<td>A device that measures the sound-noise of jaw joints when they are moving by using a microphone placed outside the oral cavity. This detects abnormal behavior of the soft tissue around the joint – e.g., articular disc – that disturbs smooth movement of the temporomandibular joint.</td>
<td>70702000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental polymerization activator</td>
<td>An electric light used to polymerize dental resin materials.</td>
<td>35775000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental cleaner</td>
<td>A device that cleans and grinds the tooth surface by polishing powder using a water jet or air jet. The devices corresponding to the active device connected tooth surface cleaner are excluded.</td>
<td>70707001</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental amalgam mixer</td>
<td>A device that shakes the amalgam plate in order to mix mercury and alloy powder placed in the dish. Usually, electrically powered. The plate is either attached or detachable.</td>
<td>10082000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental amalgam capsule</td>
<td>A capsule used to mix alloy and mercury which are individual weighed. It can be reused several times.</td>
<td>35791000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Tooth bleaching heating unit</td>
<td>A light and electric heat source used to heat the teeth after applying a dental bleaching agent or a drug-containing dental tooth surface cleaner auxiliary material to the teeth. Apparatuses that activate dental bleaching agents or drug-containing tooth surface cleaner auxiliary materials are excluded.</td>
<td>31806009</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental impression material mixer</td>
<td>An electric device used to mix impression materials immediately before use at the chair side.</td>
<td>38790000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental endodontic materials heating injector</td>
<td>A device heats and softens a root canal filling material, e.g. gutta-percha in the heating chamber attached to the handpiece, and injects it into the root canal. It is also used to soften agar impression material. Devices operated by an external energy are excluded.</td>
<td>70712001</td>
<td>I</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental root canal obstacle remover set</td>
<td>A set of devices used to remove foreign matter from the root canal such as fragments of broken root canal treatment devices.</td>
<td>70713000</td>
<td>I</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental root canal cleanser</td>
<td>A dental instrument that is attached to a handpiece, and used to remove cutting debris from the root canal, and clean the root canal. A dental instrument connected to an active device is not included.</td>
<td>70174001</td>
<td>I</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental burner</td>
<td>A burner that uses butane gas as fuel, and is used to heat or disinfect dental devices. Burners incorporated into a dental unit are excluded.</td>
<td>70715000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Description</td>
<td>Description</td>
<td>Code</td>
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</tr>
<tr>
<td>Massaging pick</td>
<td>A oral hygiene device with a sharp point that is used to manually stimulate and massage the gums and improve the periodontal (gum) condition.</td>
<td>33208000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental injector</td>
<td>A device that is used to inject dental materials inside the oral cavity or onto a tray.</td>
<td>70718000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental material thermal conditioner</td>
<td>A heating apparatus for maintaining agar impression material and other materials in the desired condition for use.</td>
<td>70720000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental implant prosthesis instrument</td>
<td>A device that is used to design, produce, dress, and fix a prosthesis used a dental implant.</td>
<td>70722000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental examination/treatment chair</td>
<td>A chair for dental treatment that secures the patient in the correct posture for dental treatment and examination. Non-electrical devices are excluded. Some allow the height and back rest to be adjusted, or have a tilting function with the body axis as pivot to optimize oral access and the visual field for the dentist. This chair is a component of a</td>
<td>34935010</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>General-purpose dental light</td>
<td>A dedicated illuminator for general dental use that illuminates targeting a specific part such as a dental surgery site, the site of an examination, or procedures (usually, inside the oral cavity).</td>
<td>12351000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental intraoral surgical light</td>
<td>A light that is used to illuminate the cavity, or a very small area.</td>
<td>12352000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthodontic ligator</td>
<td>A dental device that pushes a ligature under the arch wire or bracket wing for guiding, or pushes the arch wire or auxiliary device into a predetermiend position.</td>
<td>37413000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthodontic headgear</td>
<td>A device that is used in conjunction with an orthodontic device to apply pressure to the teeth or jaw from outside the oral cavity. A typical example of orthodontic head gear has a strap that holds the patient's neck or head and an inner bow that is fixed to the</td>
<td>31757000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthodontic chin cap</td>
<td>This chin cap is part of an orthodontic device placed outside the jaw, and applies a force to the chin toward the upper rear side.</td>
<td>41067000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthodontic band pusher</td>
<td>A manual dental device that aligns the metal band to the teeth position.</td>
<td>31801000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthodontic positioning instrument</td>
<td>A device that is used for positioning to align an orthodontic apparatus with the orthodontic band or tooth surface. Callipers used for positioning are also included.</td>
<td>70733000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Standardised cephalofacial photography appliance</td>
<td>An apparatus that is used to take a standard photo of the head or face. Used for diagnosis for orthodontic treatment.</td>
<td>70734000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Short term use orthodontic oral mucosa protector</td>
<td>A material that is used to coat an orthodontic apparatus for a short period in order to mitigate irritation to the oral mucosa caused by the apparatus.</td>
<td>70735000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Orthodontic labial muscle fixator</td>
<td>An apparatus that is used to strengthen the oral muscles, and maintain tooth alignment after the orthodontic treatment.</td>
<td>70736000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Electric lathe for dental laboratory</td>
<td>A dental laboratory use low-speed rotation apparatus that is connected to an electric motor, and cut/grind prosthesis.</td>
<td>70739000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
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</table>

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<table>
<thead>
<tr>
<th>Item Code</th>
<th>Description</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>70740000</td>
<td>High speed lathe for dental laboratory</td>
<td>A dental laboratory use high-speed rotation apparatus that is connected to an electric motor, and cut/grind prosthesis.</td>
</tr>
<tr>
<td>34699000</td>
<td>Motor for dental laboratory</td>
<td>A motor that is used with a flexible drive system in dental laboratories in order to provide a rotational force to a handpiece for dental laboratory. It is either an electric or air motor used in combination with various speed control apparatuses.</td>
</tr>
<tr>
<td>37708000</td>
<td>Dental drill remote drive</td>
<td>A device that is used to transmit a rotational force to a dental handpiece from a dental remote motor. This is designed to allow the handpiece to be operated flexibly. Designed based on a cable and pulley system or metal rotary span cable such as metal spiral.</td>
</tr>
<tr>
<td>38611009</td>
<td>Engine for dental laboratory</td>
<td>A hand-held dental device consists of one handpiece that has a chuck to connect to a rotating device such as a dental bur and reamer. This is usually placed away from the power source and connected to a flexible drive system. Electric engines for dental laboratory are included.</td>
</tr>
<tr>
<td>38611000</td>
<td>Electric engine for dental laboratory</td>
<td>A hand-held dental device for dental laboratory that consists of one handpiece that has a chuck to connect to a rotating device such as a rotary tungsten carbide cutting instrument for dental laboratory. This is usually placed away from the power source, and connected to a flexible drive system. Electric engines for dental laboratory are included.</td>
</tr>
<tr>
<td>38763009</td>
<td>Engine motor for dental laboratory</td>
<td>A dental device that has a built-in motor, and is used with a flexible drive system that provides a rotational force to the handpiece. Electrically-powered motors for dental laboratory are excluded.</td>
</tr>
<tr>
<td>38763000</td>
<td>Electrically-powered motor for dental laboratory</td>
<td>A dental device that has a built-in motor, and is used with a flexible drive system that provides a rotational force to an electric engine and handpiece for dental laboratory.</td>
</tr>
<tr>
<td>70741000</td>
<td>Trimmer for dental laboratory</td>
<td>A device that is used to trim an unsized dental plaster/stone model such as that for gnathostatic models and parallel models. Usually, it is equipped with a motor-driven grinding disk.</td>
</tr>
<tr>
<td>70742000</td>
<td>Vacuum mixer for dental laboratory</td>
<td>A stirring-kneading apparatus that is used to mixes gypsum or casting investment material with liquid, e.g. water under reduced pressure. Usually, it is equipped with a motor-driven grinding disk.</td>
</tr>
<tr>
<td>34700000</td>
<td>Remote drive drill handpiece for dental laboratory</td>
<td>A hand-held device consists of one handpiece that has a chuck to connect to a rotating device such as a bur and grinding wheel. Used at a dental laboratory. The device is placed away usually remote from the power source.</td>
</tr>
<tr>
<td>70743000</td>
<td>Dental laboratory rotary steel cutting instrument</td>
<td>A rotary cutting device has a steel working component, is attached to a dental laboratory handpiece, and is used to grind metal, plastic, porcelain, or other similar materials.</td>
</tr>
<tr>
<td>70744000</td>
<td>Rotary tungsten carbide cutting instrument for dental laboratory</td>
<td>A rotary cutting device has a tungsten carbide working component, is attached to a dental laboratory handpiece, and is used to grind metal, plastic, porcelain, or other similar materials.</td>
</tr>
<tr>
<td>70745000</td>
<td>Gas-powered dental laboratory handpiece</td>
<td>A dental laboratory device consists of one handpiece that has a chuck to connect to a rotating device such as a bur. Usually, a small turbine driven by compressed air is built in.</td>
</tr>
<tr>
<td>70746000</td>
<td>Dental laboratory electrically-powered handpiece</td>
<td>A dental laboratory device consists of one handpiece that has a chuck to connect to a rotating device such as a dental bur and reamer. A motor is built in.</td>
</tr>
<tr>
<td>70747000</td>
<td>Dental laboratory air motor</td>
<td>A dental laboratory air motor device consists of one handpiece that has a chuck to connect to a rotating device such as a bur. Usually, a small motor driven by compressed air is built in.</td>
</tr>
<tr>
<td>70748000</td>
<td>Welding/soldering instrument for dental laboratory</td>
<td>This device is used in dental laboratory to weld dental metal or metal dental crown restoration, or brazing using soldering material.</td>
</tr>
<tr>
<td>35761000</td>
<td>Curing unit for dental laboratory</td>
<td>This device is used in dental laboratory to polymerize polymeric materials at a dental laboratory. Polymerization is performed by heating, heating and pressurization, irradiation of light or a combination of these.</td>
</tr>
<tr>
<td>Product Description</td>
<td>Function</td>
<td>Code</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Dental flask</td>
<td>A container that retains the mold used to make polymer prosthesis.</td>
<td>42343000</td>
</tr>
<tr>
<td>Press for dental laboratory</td>
<td>This apparatus is used for pressing together two halves of a mould for forming and polymerization of base material when producing a removable denture in a dental laboratory.</td>
<td>34705000</td>
</tr>
<tr>
<td>Heating press for dental laboratory</td>
<td>This apparatus is used for pressing and heating together two halves of a mould for forming and polymerization of base material when producing a removable denture in a dental laboratory.</td>
<td>70749000</td>
</tr>
<tr>
<td>Moulding unit for dental laboratory</td>
<td>This apparatus is used to mold thermoplastic material by injection/pressurization, and produce a denture base or prosthesis.</td>
<td>70750010</td>
</tr>
<tr>
<td>Dental electrodeposition moulding unit</td>
<td>This apparatus is used to accumulate and mold metal or fine particles by using electrical attraction, and produce dental laboratory items.</td>
<td>70750020</td>
</tr>
<tr>
<td>High-frequency casting unit for dental laboratory</td>
<td>A device that melts and casts dental alloys using high frequency melting system.</td>
<td>70751000</td>
</tr>
<tr>
<td>Arc heating casting unit for dental laboratory</td>
<td>A device that melts and casts dental alloys using arc discharge melting system.</td>
<td>70752000</td>
</tr>
<tr>
<td>Furnace casting unit for dental laboratory</td>
<td>A device that melts and casts dental alloy using a heating furnace melting system.</td>
<td>70753000</td>
</tr>
<tr>
<td>Casting furnace for dental laboratory</td>
<td>A device used to keep the investment in a specific state and at a specific temperature in order to burn off the wax from the inlay and molds of the crown and bridge, and obtain the porcelain.</td>
<td>36180000</td>
</tr>
<tr>
<td>Casting auxiliaries for dental laboratory</td>
<td>A casting flask and casting ring used to produce dental laboratory items.</td>
<td>70754000</td>
</tr>
<tr>
<td>Porcelain furnace for dental laboratory</td>
<td>A dedicated furnace used to fire porcelain used in dental laboratory.</td>
<td>35762000</td>
</tr>
<tr>
<td>Dental articulator</td>
<td>A hinged dental device. The upper and lower jaw models are attached to this according to the intermaxillary relationship recorded in advance. Designed to simulate part or all of the movement of the lower jaw.</td>
<td>10201000</td>
</tr>
<tr>
<td>Dental facebow</td>
<td>A calipers-like dental device used to record the position of maxillary arch relative to the temporal lower temporomandibular joint (or open mouth movement axis), and align the oral model in relation to the axis of open mouth movement.</td>
<td>35700000</td>
</tr>
<tr>
<td>CAD/CAM unit for dental laboratory</td>
<td>This apparatus utilizes complex software, is installed in a workshop or dental laboratory, and used for computer aided design (CAD) or computer aided manufacturing (CAM) for dental restoration.</td>
<td>34713000</td>
</tr>
<tr>
<td>Metal surface treatment device for dental laboratory</td>
<td>A surface processor for dental laboratory that is used to add and enhance adhesion by processing the surface of dental metal.</td>
<td>70755000</td>
</tr>
<tr>
<td>Metal surface processing device for dental laboratory</td>
<td>A surface processor for dental laboratory that is used to add and enhance adhesion by processing the surface of dental metal.</td>
<td>70755000</td>
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<th>Refundable</th>
<th>Exportable</th>
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<tbody>
<tr>
<td>Pressure investing unit for dental laboratory</td>
<td>A device that is used to the lost wax casting, and is equipped with a pressurizer in order to reduce the generation of air bubbles.</td>
<td>70756000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Implant instrument/material for dental laboratory</td>
<td>Devices and materials for dental laboratory. Used to produce the upper structure of the dental implant.</td>
<td>70757000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental precision attachment fixation kit</td>
<td>Dental devices and materials used to obtain precision attachment at a desired position when producing a dental prosthesis.</td>
<td>70758000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ceramics heating pressure molding device for dental laboratory</td>
<td>A device for dental laboratory used to pressurize and mold the heated dental ceramic material. Joint cast or cast is used. Some have the function of firing dental porcelain.</td>
<td>70759000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Carver for dental laboratory</td>
<td>A device that is used to build up or sculpt the wax, plaster, resin or ceramic. In order to make the work process easier, various other materials can be supplementarily used in</td>
<td>70760000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental fusible alloy</td>
<td>An alloy used in dental laboratory that is a mixture of bismuth (≥40%), tin and lead.</td>
<td>70800000</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Dental impression tray resin</td>
<td>A powder and liquid self-curing resin, a paste-like self-curing resin or a thermoplastic resin that is used for a custom-made tray and base plate, etc.</td>
<td>70832000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental pattern resin</td>
<td>A resin is used to produce casting patterns such as inlays and crowns. Some are used for temporary adhesion in dental technical work.</td>
<td>70833000</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Dental occlusal diagnosis material</td>
<td>A material mainly made of resin, and used to evaluate the strength of a facet or assess the state of occlusion.</td>
<td>70835000</td>
<td>1</td>
<td>5-③</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental impression plaster</td>
<td>This material is primarily made of calcium sulphate hemihydrate, and used to take an oral impression.</td>
<td>34800000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental fit checking material</td>
<td>A material used to check the compatibility of the plate denture or prosthesis to the mucosal surface or abutment tooth.</td>
<td>70881000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Gingival retraction kit</td>
<td>A prepackaged kit that includes devices used for gingival retraction during abutment tooth preparation. The kit is provided as a single unit that consists of single or multiple items according to the purpose of use. Kits that include drugs are excluded.</td>
<td>16352000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Gingival retraction cord</td>
<td>A cotton thread containing no drugs that is used temporarily for gingival retraction during abutment tooth preparation.</td>
<td>35861001</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Gingival retraction material</td>
<td>A material that is used temporarily for gingival retraction during abutment tooth preparation and impression taking. Gingival retraction cord and materials that contain drugs are excluded.</td>
<td>70882000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental bite registration material</td>
<td>This material is used to record teeth occlusion, and the positional relationship between the upper and lower jaws in order to produce crowns, bridges, and denture. Dental casting wax materials are excluded.</td>
<td>70883000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental spacer</td>
<td>A thin plate made of wax or plastic. It covers the surface of an edentulous jaw ridge and teeth structure to take the primary impression. The spacer is removed from the hardened primary impression. This creates a space of a certain thickness between the oral cavity.</td>
<td>44575000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental impression taking instrument</td>
<td>Devices and materials used to take the impression. Impression trays are excluded.</td>
<td>70887000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental model duplicating agar impression material</td>
<td>This impression material is mainly made of agar, and used to produce the duplicated model.</td>
<td>70890000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Material Type</td>
<td>Description</td>
<td>Code</td>
<td>Suffix</td>
<td>Unit</td>
<td>Remarks</td>
</tr>
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</tr>
<tr>
<td>Dental model duplicating elastomeric impression material</td>
<td>This impression material is mainly made of silicone or other types of synthetic rubber, and used to produce the duplicated model.</td>
<td>70891000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Optical impression auxiliary material for dental laboratory</td>
<td>A material that is used to prevent irregular reflection when taking an optical impression using dental laboratory CAD/CAM unit. This is used to take the impression from the model.</td>
<td>70892000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental casting wax</td>
<td>A dental casting wax is used to produce the wax mold for fixed prosthesis restoration by the lost wax casting method.</td>
<td>16189000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental paraffin wax</td>
<td>This casting wax is mainly used for a trial denture and arrangement of artificial teeth.</td>
<td>70893000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental casting sheet wax</td>
<td>A wax is used to produce a cast wax pattern of denture base, bar and clasp.</td>
<td>70894000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental sticky wax</td>
<td>A wax for temporary adhesion is used to produce dental laboratory items.</td>
<td>70895000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bite registration rim</td>
<td>A preliminary model of the dental arch is attached to the trial denture or the permanent base in order to record the relationship between the upper and lower jaws. The occlusal rim is produced and adjusted for individual patient based on the existing molds.</td>
<td>18083000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental impression wax</td>
<td>This material is used to take an oral impression. Made of wax. Some materials are mixed with resin having a low melting point.</td>
<td>34807000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Bite registration rim wax plate</td>
<td>Dental materials (model wax) used to record the relationship between the upper and lower jaws. Molded like a plate, and used to produce the occlusal rim. Some are reinforced with foil (metal, plastic).</td>
<td>38584000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Bite registration rim wax</td>
<td>Dental materials (model wax) used to record the relationship between the upper and lower jaws. Used to produce the occlusal rim. Some are reinforced with foil (metal, plastic).</td>
<td>38602000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental utility wax</td>
<td>This multipurpose wax is supplementarily used for producing dental laboratory items.</td>
<td>70896000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental base plate</td>
<td>This base plate is used as the foundation when build up the occlusal rim, or producing denture for trial application. The dental base plate is made of wax, shellac or polymer, and produced for individual patients (individual production)</td>
<td>34808000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental general-purpose wax</td>
<td>A wax is used to take an oral impression, wax pattern of a trial application, and produce the pattern of the inlay and the crown. Waxes that are given other names are excluded.</td>
<td>31836010</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Molded dental wax</td>
<td>This material is used to produce a device that maintains a removable partial denture. It is molded with wax to a prescribed configuration, and may be replaced with metal by casting.</td>
<td>31836020</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental pattern cast</td>
<td>A ready - made pattern used to produce restorations. Made of wax or resin. Molded dental wax are excluded.</td>
<td>31836030</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Material Type</td>
<td>Description</td>
<td>Tax Code</td>
<td>Customs Tariff Description</td>
<td>Material Code</td>
<td>Duty Rate</td>
</tr>
<tr>
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</tr>
<tr>
<td>Dental baked plaster</td>
<td>Calcined gypsum is used as a model material to produce dental laboratory items.</td>
<td>70897010</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental stone</td>
<td>A dental stone used as a model material to produce dental laboratory items.</td>
<td>70897020</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental refractory modelling material</td>
<td>This model material for high-temperature processing is primarily made of anhydrous silicic acid, phosphate, colloidal silica, and ethyl silicate.</td>
<td>70898000</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental refractory modelling auxiliary material</td>
<td>This material is used to enhance the strength of a dental refractory model.</td>
<td>70899000</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental polymer-based modelling material</td>
<td>This material is made of various polymers, and is used in the production of dental models and restorations.</td>
<td>34811000</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental gypsum-bonded casting investments</td>
<td>This casting investment material is primarily made of anhydrous silicic acid and gypsum.</td>
<td>70900010</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental casting investments for high-fusing alloy</td>
<td>This casting investment material is primarily made of anhydrous silicic acid, alumina, magnesia, phosphate, colloidal silica, ethyl silicate, and gypsum.</td>
<td>70900020</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental brazing investment material</td>
<td>This brazing investment soldering material is primarily made of quartz and binders.</td>
<td>70900030</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable dental abrasive point</td>
<td>A device that is used to remove excessive filler such as dental composite resins for restoration, and to grind or polish the restorations such as a crown. This device is reusable.</td>
<td>31833000</td>
<td>I 6 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abrasive point for dental laboratory</td>
<td>A silicon carbide, and alumina, etc. are used as the material for grinding in dental laboratory. The point, wheel, and disk are included.</td>
<td>70901000</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diamond abrasive point for dental laboratory</td>
<td>Diamond is used as the material for grinding in dental laboratory. The point, wheel, and disk are included.</td>
<td>70902000</td>
<td>I 1 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental prophylaxis cup</td>
<td>A cup usually made of rubber, and used when a grinding material is used for dental abrasive (cleaning). The cup attached to the dental handpiece is rotated when the grinding material is applied to the teeth.</td>
<td>16184000</td>
<td>I 6 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental rubber abrasive</td>
<td>A dental abrasive with various grinding components on the rubber base material. The point, wheel, and disk are included.</td>
<td>70903000</td>
<td>I 6 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental abrasive strip</td>
<td>A dental strip with grinding particles coated on one or both sides. Used to grind the surface of teeth or restorations.</td>
<td>35702000</td>
<td>I 5 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental-professional teeth cleaning brush</td>
<td>A rotary dental brush used for cleaning and polishing by a dental hygienist or a dentist.</td>
<td>35768000</td>
<td>I 5 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tooth abrasive</td>
<td>A powder, paste, cream or gel-like semi-solid abrasive used for cleaning and grinding the tooth surface by a dental hygienist and a dentist. A prophylaxis and treatment brush, and tooth polishing cup are used to grind the tooth surface. Materials intended for biological</td>
<td>70904000</td>
<td>I 5 N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>Density</td>
<td>Category</td>
<td>Remarks</td>
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</tr>
<tr>
<td>Abrasive/polishing device kit for dental laboratory</td>
<td>A kit that consists of grinding materials and abrasive for dental laboratory.</td>
<td>70906000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental polishing device</td>
<td>A material used for polishing the prosthesis. Items that are given different names are excluded.</td>
<td>70907000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental abrasive device</td>
<td>A material used for grinding the prosthesis. Items that are given different names are excluded.</td>
<td>70908000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental glove</td>
<td>Rubber or plastic gloves used when performing dental examinations, treatments or other procedures. Surgical gloves are excluded.</td>
<td>70911000</td>
<td>1</td>
<td>5-①</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental matrix band</td>
<td>A band or short tube that is made of stainless steel or polyester. It provides the general outline of the restorative material, and holds the restorative material. The band is attached to the desired position by the matrix retainer (a device that fits this band around the teeth without any gap). The outline is formed according to the configuration of the tooth to be restored and the position of adjacent teeth.</td>
<td>16195000</td>
<td>1</td>
<td>5-③</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental matrix wedge</td>
<td>A dental device that is inserted into the tooth cervix so as to slightly separate the teeth when inserting the filling material.</td>
<td>16370000</td>
<td>1</td>
<td>5-③</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental matrix retainer</td>
<td>This retainer retains the matrix band at the desired position on the teeth.</td>
<td>33204000</td>
<td>1</td>
<td>5-③</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental occlusal splint</td>
<td>A rigid or flexible material that covers the occlusal surface. Used to retain the position of a malpositioned tooth or loose tooth, to treat clenching (habitual clenching), bruxism and its aftereffects, and for temporary analgesia of pain in the muscles or temporomandibular joint, e.g., temporomandibular joint disorder. It should not be used for a period exceeding 30 days.</td>
<td>36311000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental molded polymer clasp</td>
<td>A ready-made dental clasp made of polymeric materials. It should not be used for a period exceeding 30 days.</td>
<td>38625000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental molded metal clasp</td>
<td>A ready-made, elastic metal clasp used for removable partial denture. It should not be used for a period exceeding 30 days.</td>
<td>70912000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Dental occlusal splint material</td>
<td>Materials used to produce dental occlusal splint. They should not be used for a period exceeding 30 days.</td>
<td>70914000</td>
<td>1</td>
<td>5-③</td>
<td>applicable</td>
</tr>
<tr>
<td>Retention bead for dental laboratory</td>
<td>Minute synthetic resin beads used for casting patterns. The beads form minute protrusions on the metal coping surface in order to retain the resin surface when producing a resin facing crown.</td>
<td>70915000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ceramic surface treatment material for dental laboratory</td>
<td>A technical material for surface treatment that is used to provide or enhance the adhesiveness of the dental ceramic surface. Materials do not stay on the surface of a dental crown restoration etc.</td>
<td>70918000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Code</td>
<td>5-digit Code</td>
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</tr>
<tr>
<td><strong>Dental material separator</strong></td>
<td>A separator used in the oral cavity. Used for the separation of the denture base or artificial/natural teeth and dental material, or between dental materials.</td>
<td>70923000</td>
<td>5-1</td>
<td>applicable</td>
<td>−</td>
</tr>
<tr>
<td><strong>Dental marker</strong></td>
<td>A marker used to assess the strength of the facet, and for positioning.</td>
<td>70925000</td>
<td>5-3</td>
<td>applicable</td>
<td>−</td>
</tr>
<tr>
<td><strong>Dental oral cavity cleaning kit</strong></td>
<td>A kit that contains a prophylactic treatment brush, prophylactic cup, dental floss, and abrasive. The kit is used by a dentist and dental hygienist for tooth surface cleaning.</td>
<td>70927000</td>
<td>5-1</td>
<td>N/A</td>
<td>−</td>
</tr>
<tr>
<td><strong>Dental endodontic instrumentation aid material</strong></td>
<td>A material used to soften and neutralize the calcified root canal wall during dental treatment. Some are provided as a set that includes the devices used with materials. Drug-containing materials are excluded.</td>
<td>70928001</td>
<td>5-1</td>
<td>applicable</td>
<td>−</td>
</tr>
<tr>
<td><strong>Ear knife</strong></td>
<td>A special surgical severing device used in surgery of anatomical structures of the ear. The handle comes in various configurations. The handle is tapered, forming a thin shaft to which a small blade is attached.</td>
<td>12245000</td>
<td>6-1</td>
<td>N/A</td>
<td>−</td>
</tr>
<tr>
<td><strong>Manually-operated keratome</strong></td>
<td>A manually operated ophthalmic surgical device used for incision of cornea.</td>
<td>12220001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Knife handle</strong></td>
<td>A metal (usually, stainless steel) surgical device to which a blade for tissue severing or resection is attached.</td>
<td>12235000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Orthopaedic osteotome</strong></td>
<td>A surgical device with a cutting blade. Used for osteotomy (surgical cutting of bones). The severed bone is usually used for transplantation. This device is also used for osteoplasty.</td>
<td>12844000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Sclerotome</strong></td>
<td>An ophthalmic surgical device used for incision of sclera.</td>
<td>13507001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Bone trephine</strong></td>
<td>A device used to sever and remove an intervertebral disk.</td>
<td>14147000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manual corneal trephine</strong></td>
<td>A cylindrical, manual ophthalmic surgical device that has a blade at the end, and is used to sever and remove ring-like pieces of corneal tissue (corneal button). If healthy tissues are collected from a deceased person for transplantation, cornea displaying signs of abnormality is cut off and removed.</td>
<td>14148001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Sacculotomy tack</strong></td>
<td>A device that is used to puncture the saccule in order to remove the labyrinth lymph node from the inner ear.</td>
<td>16080000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Ophthalmic knife</strong></td>
<td>A surgical severing device that has a handle and a blade and comes in various configurations and sizes. Used for the surgery of the eye and surrounding structures.</td>
<td>32764001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Instrument</td>
<td>Description</td>
<td>KANEOHE</td>
<td>6-digit</td>
<td>Classification</td>
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</tr>
<tr>
<td><strong>Ophthalmic cystitome</strong></td>
<td>An ophthalmic surgical device used to cut the ocular crystalline lens capsule.</td>
<td></td>
<td>34984000</td>
<td>1</td>
<td>6-① N/A N/A</td>
</tr>
<tr>
<td><strong>Knife</strong></td>
<td>A device used for severing and resecting tissue during surgery. Usually, it is designed as a surgical device with a handle and a blade that come in various configurations and sizes. The devices classified as a knife are designed to sever by using other techniques. Some are used to cut samples and other objects as well as tissues.</td>
<td>35130001</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Gingivectomy knife</strong></td>
<td>A severing instrument used to resect the soft tissue wall of the pocket.</td>
<td>41544000</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Syndesmotome</strong></td>
<td>A dental surgical device used to sever the ligament fibers and separate the alveolar part.</td>
<td>42338000</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Dental surgical tissue scissors</strong></td>
<td>Scissors specifically designed for dental surgery.</td>
<td>31822000</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Dental collar/crown scissors</strong></td>
<td>A dental scissors have straight or curved short blades designed to sever metal band.</td>
<td>31847000</td>
<td>1</td>
<td>1</td>
<td>N/A N/A</td>
</tr>
<tr>
<td><strong>Scissors</strong></td>
<td>Scissors usually used to sever tissue, cloth, or sutures during surgery. The two blades meet at the pivot (Usually, they have a hole at each handle for the thumb and other fingers respectively). The blades are closed to sever the material</td>
<td>35325001</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Ophthalmic scissors</strong></td>
<td>An ophthalmic surgical device used to sever tissue in ophthalmic surgery. Some have two rotary blades or handles gripped by the thumb and other fingers. The blade comes in various configurations.</td>
<td>35327001</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Line operated autopsy saw</strong></td>
<td>A hand-held saw has a round rotary blade, and is connected by a cable to a power source or a battery. It is usually used to cut/dissect the upper cranial bone. Some are equipped with a removal unit that has a container for collecting tissue and bone fragments</td>
<td>44142000</td>
<td>1</td>
<td>6-① applicable</td>
<td>ー</td>
</tr>
<tr>
<td><strong>Manually-operated autopsy saw</strong></td>
<td>A manually operated hand-held device that has a saw-like blade. Used to sever bone during an autopsy.</td>
<td>44143000</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td>ー</td>
</tr>
<tr>
<td><strong>Gas-powered autopsy saw</strong></td>
<td>A gas-powered hand-held device that has a round rotary blade. Usually used to dissect the upper cranial bone during an autopsy. Some are equipped with a removal unit that has a container for collecting tissue and bone fragments. Usually, compressed air is the power source</td>
<td>44144000</td>
<td>1</td>
<td>6-① applicable</td>
<td>ー</td>
</tr>
<tr>
<td><strong>Surgical saw</strong></td>
<td>A manual or power-operated (e.g., air, nitrogen, battery or power source) device. Used as a single unit, or with various attachments such as a vibrating blade and reciprocating blade. Usually used exclusively for a specific purpose. It adopts either a micro or macro</td>
<td>13448001</td>
<td>1</td>
<td>6-① N/A N/A</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Quantity</td>
<td>Unit</td>
<td>N/A</td>
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</tr>
<tr>
<td>Cast cutter blade</td>
<td>A surgical blade that comes with a cast removal device (cast cutting saw), and is used to cut the cast material.</td>
<td>15774000</td>
<td>1</td>
<td></td>
<td>6-1</td>
</tr>
<tr>
<td>Powered cast cutter</td>
<td>Usually, a hand-held electric device that has a cylindrical handle at the proximal end, and a semi-circular blade at the distal end which is used to cut a cast made of plaster or synthetic material. The blade electrically cuts by a motor installed in the handle that.</td>
<td>16340000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Manually-operated cast cutter</td>
<td>A hand-held scissors-like device has two blades. The distal end to the pivot of the blades forms various jaw-like structures. Used to cut a cast made of plaster or synthetic materials. The tip of one blade is made blunt so as not to cause damage to the patient.</td>
<td>16341000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Saw</td>
<td>A manual or power-operated (e.g., air, nitrogen, battery or power source) device that is used to cut or separate an anatomical structure or object. Used as a single unit, or with various attachments. Usually used for a specific purpose.</td>
<td>34821001</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Chisel</td>
<td>A surgical device that has a blade with an oblique angle on one side. Used to sever bone and other hard tissues or sever out the outline.</td>
<td>10824000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>File</td>
<td>A hand-held manual surgical device that has a rough surface and which comes in various configurations. Used to smooth, grind or sever tissue.</td>
<td>11701001</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental margin finishing file</td>
<td>This finishing file is a metal manual dental device that has a fine mesh surface which is used to finish the margins of the tooth or other dental restorations.</td>
<td>31863000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Corneal bur instrument</td>
<td>A small hand-held rotary surgical device that consists of a steel or other hard alloy shaft that has a groove cutter or cutter in various configurations at the end. Used for curettage of corneal tissue.</td>
<td>35786000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental plastic filling material file</td>
<td>A dental instrument that has grooves on one side. Used to finish the margins of plastic filling material.</td>
<td>37629000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic snare</td>
<td>A surgical device that is used to arrange a flexible wire loop around tissue for resection, and snare it. Usually used for eyeball removal. Some consist of a channel or cannula, 2 fixed rings and a sliding ring, and used in ophthalmic surgery.</td>
<td>32755001</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Snare</td>
<td>A device usually consists of a channel or cannula, 2 fixed rings and a sliding ring. It is used to arrange a flexible wire loop around tissue, and snare it. The sliding ring is moved relative to the fixed rings so as to control the length of the wire extended from the channel.</td>
<td>34822000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Adenotome</td>
<td>A surgical device used to dissect the adenoids.</td>
<td>10025000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Tonsillectome</td>
<td>A manually operated surgical device used to dissect the tonsils. It comes in a flexible loop that holds the tonsil, or a metal frame with a sliding blade. The loop type holds the tonsil, allowing an incision to be made with a manual knife. The frame type has a manual crank.</td>
<td>14070000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable resection blade</td>
<td>A surgical blade that is used to push the adenoid tissue into the guillotine cutter of the adenoid dissector. This device is reusable.</td>
<td>35836000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Isisable</td>
<td>Usage</td>
<td>Remarks</td>
</tr>
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</tr>
<tr>
<td>Cranial bur</td>
<td>Usually a small rotary shaft made of steel or other hard metal. It has a groove cutter or cutter in various configurations on one end. Used to open a hole in soft or hard cranial tissues. Attached to an appropriate electric device to effect rotation.</td>
<td>10520001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable airway needle</td>
<td>A device with a sharp point which is used to open the airway. Usually, made of hollow metal. Used for emergency cricothyroidectomy in patients with respiratory occlusion. This device is reusable.</td>
<td>12732001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Perforator</td>
<td>Usually a stainless steel device is used to pierce through soft tissue or bone. The spear-shaped shaft has a handle at the proximal end, and a spear or conical configuration at the distal end. Some have a tong-like configuration that is moved when the handle is.</td>
<td>12989001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Skin graft mesh dilation dermatome</td>
<td>A manual device used to form patterned cuts on the donor's skin piece before grafting. Usually, when the skin is fed into the cutting wheels (the skin is stretched to a certain extent), small slit-like holes are formed. This procedure ensures better skin grafting and healing.</td>
<td>13614000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Guide</td>
<td>A trocar guide rod, which is used for trocar sleeve replacement, and other apparatuses, devices or accessories used to guide an object in a desired direction. This guide is used in the following cases: 1. Slow introduction or operation on a site difficult to access when other techniques fail.</td>
<td>37150000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Pneumatically-powered cast cutter</td>
<td>A hand-held pneumatic saw. Usually it has a cylindrical handle at the proximal end, and a semi-circular blade at the distal end that cuts a cast made of plaster or synthetic materials. The blade performs the cutting movement by means of an air motor installed in the handle that vibrates the blade. Cutting is effected by vibration, not by a sawing motion.</td>
<td>17523000</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Wire cutter</td>
<td>A scissors-like surgical device that has 2 blades. Used to cut the wire, pins or connected parts.</td>
<td>32885000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical guillotine</td>
<td>A cutter that consists of a metal frame. The cutter slides through the frame. It comes in various configurations and sizes according to the type of tissue to be severed. Various cranks or shaft driver mechanisms generate the power.</td>
<td>35096000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Malleus cutter</td>
<td>A cutter has ring handles. One blade from the distal end to the pivot slides back and forth, and manipulates the cutting part. Some have a sharp anvil or clasp at the end of the fixed blade. The one with an anvil at the end has a sliding blade that opens and closes the other sharp blade to the anvil. The one with a clasp at the end has a sliding blade that touches the clasp.</td>
<td>35213000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Blood vessel surgical stripper</td>
<td>A surgical device used to resect part of a blood vessel. Some strippers are designed to sever part of a vein or artery. There are two kinds of surgical blood vessel stripper: One is a flexible stainless steel cable that has a stripping cup or disk on one end, and a guide tip attached. The other is a handheld lever that has a stripping cup or disk on one end, and a guide tip attached.</td>
<td>35377001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dermatome</td>
<td>A surgical knife used to harvest the skin for grafting. Either manual or electric-powered.</td>
<td>36432000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable dermatome blade</td>
<td>A blade that comes in various sizes, attached to the skin graft knife, and is used to harvest the skin graft. This device is reusable after sterilization. Usually, the blade point should be sharpened periodically.</td>
<td>37472000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Gas-powered dermatome</td>
<td>A gas pressure-operated surgical device used to cut a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.</td>
<td>35473000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Gas-powered surgical saw</td>
<td>A saw has a handpiece with an attachment that generates vibration or reciprocal movements. It adopts either a micro or macro design. Rechargeable batteries are used. Usually, compressed air or compressed nitrogen is used.</td>
<td>37841000</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Soft tissue trephine</td>
<td>A cylindrical or coronary saw used to resect discs of tissues other than bones. It comes in various sizes and configurations according to the size and hardness of the tissue to be resected.</td>
<td>38440000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Manually-operated dermatome</td>
<td>A hand-held surgical device used to sever a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.</td>
<td>38797000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Description</td>
<td>Details</td>
<td>I</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td>Reusable ophthalmic forceps</td>
<td>A forcep used to hold, operate, press, pull or connect the ocular tissue and the surrounding tissue. Some have two blades and two handles connected to the blades, and are used for surgery. Usually, other have detachable handles which are attached by pressure before.</td>
<td>16209001</td>
<td>6-38</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental articulation paper tweezers</td>
<td>A dental forceps have a spring at each point, and are used to hold the occluding paper.</td>
<td>31813000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental tweezers</td>
<td>A manual dental forcep have a tapered spring at each point. These points are to hold the wound cover or protection material used in the earl cavity.</td>
<td>31814000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Forceps</td>
<td>A surgical device that has two blades which are closed to hold an object. The handles are permanently connected to the forceps. This category includes all surgical forceps, micro-forceps and surgical tweezers.</td>
<td>35079001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Pylorus separator</td>
<td>A set of forceps used to separate the gastrointestinal tissue such as pylorus (distal end of the stomach) from the neighboring tissues during surgery. Usually, this device is made of stainless steel.</td>
<td>13543000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Tonsil forceps</td>
<td>A surgical device that has two blades which are connected at the proximal end to the handles (some are used like scissors which have a pivot). Usually, it is used to hold and manually operate the tonsile during tonsillectomy.</td>
<td>15672000</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable forceps</td>
<td>A surgical device that is used to hold, connect, press and support an organ, tissue or blood vessel non-traumatically. This device is reusable.</td>
<td>10861001</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable circumcision surgical clamp</td>
<td>A surgical device that is used to press the foreskin of the penis during prepuhtomy. This device is reusable after sterilization.</td>
<td>10869000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use nose clip</td>
<td>A device that is used to block the passage of air through the nostrils. The clip is usually made of rubber, plastic or foam tips, and used to test the pulmonary function. The clips are used to ensure that air flows through the mouthpiece for accurate measurement. This device is for single-use.</td>
<td>10907000</td>
<td>1</td>
<td>N/A</td>
<td>–</td>
</tr>
<tr>
<td>Dental forceps</td>
<td>A dental forcep used to remove the alveolar crest after tooth extraction.</td>
<td>15713000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Tube introduction forceps</td>
<td>A scissors-like device with ring handles. The distal end of the blade forms a ring with a saw blade, which is used to insert an endotracheal tube. The blade at the center is S-shaped, or curved.</td>
<td>31264000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical forceps</td>
<td>A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues. Usually, it is sturdy enough to withstand the force required to clamp the tissue. They come in various designs such as a plier type, pistol grip type and the pistol.</td>
<td>32853000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthodontic plier</td>
<td>A small pliers have a point that takes various configurations according to the purpose of use. Used to hold a small object, bend and cut a metal piece or wire.</td>
<td>33209000</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Stone removal forceps</td>
<td>A surgical device that is used to hold, handle and remove a urinary stone or gallstones. It consists of two blades that have a handle at each end. Some have permanently connected handles, and others have handles that are attached by pressure before use. Other devices can also be used for lithotomy.</td>
<td>35083000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental extraction forceps</td>
<td>A surgical device that is used to hold, connect, press or support the ocular tissue or the surrounding tissue non-traumatically.</td>
<td>35552000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Forceps for dental laboratory surgical</td>
<td>A dental laboratory instrument used to bend, sever and create a bulge in metal strips and wire, and break plaster or other. Electricall instrument are excluded.</td>
<td>70935000</td>
<td>1</td>
<td>N/A</td>
<td>–</td>
</tr>
<tr>
<td>Instrument Name</td>
<td>Description</td>
<td>Code</td>
<td>Category</td>
<td>Count</td>
<td>Code Type</td>
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</tr>
<tr>
<td>Ophthalmic surgical clamp</td>
<td>A surgical device used to hold, connect, press or support the ocular tissue or the surrounding tissue non-traumatically.</td>
<td>35801000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Dental root separator</td>
<td>A separator is a dental surgical instrument specifically designed to be inserted between the mandibular teeth, and create a gap between them.</td>
<td>42339000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT cupped forceps</td>
<td>A forcep with a spoon-(dish) like configuration at the distal end, and is used to treat the ear, nose, and throat (ENT), and remove tissue from the body.</td>
<td>70936000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Percutaneous tracheostomy forceps</td>
<td>A forcep used to bluntly dilate the gap between tracheal cartilages, and create an orifice for percutaneous tracheostomy. The guide wire can be inserted into their tip to achieve an accurate approach to the tracheostomy site.</td>
<td>70938000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Tongue depressor</td>
<td>A surgical instrument used to move the tongue to facilitate examination of surrounding organs and tissue.</td>
<td>14066000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Trabeculotomy surgical probe</td>
<td>A thin metal rod used for trabecular meshwork surgery. Some are used to incise the trabecular meshwork from outside the eye.</td>
<td>32761000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical probe</td>
<td>A surgical device is a thin rod made of metal or flexible material. It is used to examine cavities, fistulas, and other hollow structures and wounds. Design of its tip of probe varies depending on the specific anatomical purpose (e.g., examination of mastoid). Some bend and form a right angle with the shaft. This device is reusable.</td>
<td>32870001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic probe</td>
<td>This device is a thin rod made of flexible metal, and has a round point. Used to examine the eyes and related structures.</td>
<td>35251000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Urinary tract sizer</td>
<td>A device used to measure the internal diameter of the urinary tract in order to select a device of a suitable size.</td>
<td>70939000</td>
<td>I</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic Flieringa ring</td>
<td>A loop-like band usually made of stainless steel that is sutured onto the sclera to prevent the eyeball from being crushed during difficult ocular surgery.</td>
<td>32758000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Fornixscope</td>
<td>An ophthalmic device used to lift the eyelid and keep the eye open during a conjunctiva examination.</td>
<td>32708000</td>
<td>I</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Eye speculum</td>
<td>A device used to lift the eyelid and keep the eye open in ophthalmic surgery or examination. Some are a surgical device that consists of 2 arms connected at the pivot, and comes in various sizes, configurations and profiles. Some have a round distal end which is inserted in order to dilate and stretch the tissue around the ocular cavity. Used</td>
<td>35349001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Applier</td>
<td>This surgical device is used to apply surgical clips, staples or other medical devices to the tissue.</td>
<td>16446000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Description</td>
<td>Description</td>
<td>Code</td>
<td>Level</td>
<td>Risk</td>
<td>Notes</td>
</tr>
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</tr>
<tr>
<td>Incontinence surgical clamp</td>
<td>A surgical device designed to press the urethra non-traumatically from outside to cause enuresis. It consists of a malleable metal frame, and is partially coated with sponge rubber.</td>
<td>35119000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Skull surgical clamp</td>
<td>A surgical device used to hold the skull during surgery in order to fix the head and neck at the desired position during surgery. Usually used for neurosurgery.</td>
<td>35446000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Intraocular lens inserter</td>
<td>A device inserted into the eye to guide the insertion and positioning of the intraocular lens during surgery. The device is removed after the intraocular lens is inserted.</td>
<td>36061001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use penile surgical clamp</td>
<td>A surgical device used to pinch and handle the penis during surgery. This device is for single-use.</td>
<td>38523000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use circumcision surgical clamp</td>
<td>A surgical device used to pinch the foreskin of penis during posthethomy. This device is for single-use.</td>
<td>38525000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use hemorrhoid surgical clamp</td>
<td>A surgical device that resembles scissors and has ring handles. The blade from the pivot to the end has a triangular jaw with saw-like teeth. This device is for single-use.</td>
<td>38526000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Endoscopic surgery introducer and extractor</td>
<td>A cylindrical device that is used to insert devices and remove resected tissue during endoscopic surgery.</td>
<td>70940000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical clamp cover material</td>
<td>A device that is made of plastic to cover the clamp jaw to protect body during temporary non-traumatic compression and hemostasis. The device is for single-use.</td>
<td>70941000</td>
<td>I</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Lens expressor</td>
<td>A manual ophthalmic surgical device used to remove the nucleus lentis from the eye.</td>
<td>12318000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable ophthalmic curette</td>
<td>An ophthalmic surgical device has an end with a fenestrated, spoon, or ring in shape, and is used for abrasion. Some have a sharp point and others have a round point. Used to collect and resect the ocular tissue. This device is reusable.</td>
<td>32772001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable lens surgical spoon</td>
<td>A manual ophthalmic surgical device used to handle and resect the eye lens during eye lens surgery. This device is reusable.</td>
<td>35153001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Stone extractor</td>
<td>A surgical device used to remove stones (e.g., kidney stones, gallstones) from the body. According to the surgical method adopted, it comes in various configurations and designs. Usually, it has the long, flexible distal end equipped with a dilation mechanism (e.g., basket at the distal end). It comes in a spoon-like configuration and various other structures.</td>
<td>35808000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Item Description</td>
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<td>Code</td>
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</tr>
<tr>
<td>Reusable cornea mill</td>
<td>An ophthalmic surgical device that is used to remove the &quot;rust ring&quot; from the cornea. This device is reusable.</td>
<td>37241000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable spoon</td>
<td>A device with a handle that has a spoon-(dish) like configuration at the distal end, and a handle. Used as a surgical device, a device to administer a drug, or another function at medical departments. This device is reusable.</td>
<td>41716001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable ring curette</td>
<td>A device with a handle that has a hollow configurations like a ring at the distal end, and a handle. Used to curette lesion tissue and other body tissues. This device is reusable.</td>
<td>70942000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable orbit retractor</td>
<td>An ophthalmic surgical device used to push aside the edge of a dissected eye and other structures, or fix the eyeball. This device is reusable.</td>
<td>13381001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Orbital depressor</td>
<td>An ophthalmic surgical device used to push aside the tissue so as to make it easy to test the site around the orbital cavity in ophthalmic surgery.</td>
<td>16465000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable ophthalmic hook</td>
<td>A surgical device comes in various configurations, and has a shaft-like handle that tapers towards the distal end. Some have a distal end with curved or bent, and have a tip with round or sharp. This device is reusable.</td>
<td>32767000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical claps</td>
<td>A surgical device has a shaft-like handle. The handle comes in various configurations, and tapers towards the distal end. The distal end is either a round point, curved toward the sharp point, or bent.</td>
<td>35105000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Orbital retractor</td>
<td>An ophthalmic surgical device has 2 broad clasps with a curved point at the handle. The edge of the clasp is not sharp, and is notched so as to push aside the tissue around the orbit during examination or treatment.</td>
<td>35314001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic retractor</td>
<td>An ophthalmic surgical device used to push aside the edges of an incision of the eye and related structures.</td>
<td>70943000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic surgical lid plate</td>
<td>A lid plate that is inserted between the cornea and eyelid so as to protect the cornea during eyelid surgery. Made of plastic or metal.</td>
<td>70944000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Scleral plug</td>
<td>A nail-like plug used to be inserted into a wound temporarily to close the wound when the tip inserted into the wound is removed during vitreous body surgery.</td>
<td>70945000</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable retractor</td>
<td>A surgical device used to separate the tissues or other anatomical sites. It exposes the organ or tissue concerned, and enables access to them for examination or treatment. This device is reusable.</td>
<td>13373001</td>
<td>I</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Instrument</td>
<td>Description</td>
<td>Code</td>
<td>Usage</td>
<td>Brand</td>
<td>Notes</td>
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<tr>
<td>Dental retractor</td>
<td>A manual dental instrument used to push aside and protect the soft tissue to provide better visibility and access during surgery.</td>
<td>13380000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Urological retractor</td>
<td>A retractor designed to retain the anatomical structure of the bladder, and have a frame-like structure in which a retractor blade is installed. Some are not sharp, and others have a clasp like appearance (or have more than one clasp). Used to push aside the edges of the incised wound, organ or tissue during surgery.</td>
<td>35311000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Laparoscope mechanical distension unit</td>
<td>An apparatus used to mechanically lift up the abdominal wall so as to make a space in the abdominal cavity for a laparoscopic procedure. The abdominal wall is lifted up by an extracorporeal lifting mechanism (e.g., manual traction device, support arm winch, and arm support winch). Some may have ring handles. The opposite end of the blade to the pivot forms a handle.</td>
<td>36302000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Rigid direct anoscope</td>
<td>An autoclave used to observe, diagnose, and treat the anal canal and the lower part of the rectum. Some are equipped with a light and dilation apparatus.</td>
<td>10156001</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Vaginoscope</td>
<td>An autoclave usually used for pediatric vaginal examination. It consists of a coloscope, cold light device, and dilation apparatus. Usually used to search for foreign matter or bleeding site.</td>
<td>15630000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Direct sphincteroscope</td>
<td>An autoclave used for anal sphincter examination. Some are used to examine up to the rectum.</td>
<td>15787001</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Speculum</td>
<td>A surgical device consists of 2 arms connected at the pivot. It comes in various sizes, configurations and profiles. It has a round distal end which is inserted, dilates and extends the body cavity, orifice and lumen in order to open a hole. Used for examination or insertion of other devices. Usually, it is made of stainless steel, or plastic. The arms near the pivot usually form handles. The arms away from the pivot open when the handles are gripped together.</td>
<td>35517000</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Vascular tunneller</td>
<td>A stainless steel surgical device usually used to produce tunnels along the vascular tissue in order to produce connected channels. Usually, it is a flexible or rigid rod with a handle tapered to the rod. It has a button or an acorn-shaped knob at the distal end. Some have the pivot near the distal end, slightly curved long blades, and ring handles. The opposite end of the blade to the pivot forms a short narrow arm. Some have a pivot near the distal end.</td>
<td>35950009</td>
<td>6-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Indirect laryngoscope</td>
<td>A device consists of a rod-like holder with a tilted mirror at the end. Used for observation, diagnosis, and treatment of the pharynx and surrounding tissues.</td>
<td>70947000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Intubation laryngoscope</td>
<td>A laryngoscope used to assist the insertion and placement of an endotracheal tube into the trachea, or eliminate foreign matter in order to secure the airway (human airway) for anesthesia or emergency medical care. Used for observation, diagnosis, and treatment of the larynx and surrounding tissues. It consists of a handle and a blade. Some are equipped with a lighting apparatus. The &quot;flexible laryngoscope for intubation.&quot; &quot;rigid&quot;</td>
<td>70948009</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Occlusal retractor</td>
<td>A dental instrument used to keep the patient's mouth open during dental treatment.</td>
<td>70949000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Nasal breath mirror</td>
<td>A polished metal piece fogsy up due to the water vapor emitted from the nasal cavity when placed near the nasal cavity. The device is used to assess ventilation via the nasal cavity.</td>
<td>70950000</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Endoscopic mouthpiece</td>
<td>A device that is used to keep the patient's mouth open during the use of endoscope.</td>
<td>70951000</td>
<td>5-1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Type</td>
<td>Grade</td>
<td>Notes</td>
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</tr>
<tr>
<td>Metreurynter</td>
<td>An inflatable bag used to dilate the uterine cervix.</td>
<td>12524000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Colostomy rod</td>
<td>A rod that is placed through the colon loop in order to temporarily keep the colon loop pulled out of the abdominal wall via the surgical orifice, and prevent the colon loop from returning to the inside during loop colostomy.</td>
<td>31987000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Salivary gland dilator</td>
<td>A surgical device used to dilate the cavity, tube and orifice of the salivary gland during ear, nose and throat (ENT) surgery.</td>
<td>35830000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dissector</td>
<td>A hand-held surgical device usually has a spoon-like or round cutting component made of stainless steel. Used to separate the soft tissue or body structure from other tissue or structures. It comes in various configurations and sizes. Usually, it has a handle at the proximal end, and a shaft at the other end. The end of the shaft is pointed, flat, sharp or blunt. Some are bent away from the shaft, and others are straight.</td>
<td>11290000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Levator</td>
<td>A surgical device that is used to lift, place, and push up with a lever the tissue or other anatomical structure, surgical material or device. It has a handle at the proximal end, and a blunt blade, or a clamp with no blade at the end of the handle. It comes in various forms.</td>
<td>11504000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Tendon surgical stripper</td>
<td>A surgical device consists of a semi-circular groove that has a handle and a blade with a sharp point. The stripper is used to resect the whole length of the ligament, tendon and myelin used as biological graft.</td>
<td>35380000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Elevator</td>
<td>A device that is used to strip off the tissue during general surgery. Electrical devices are excluded.</td>
<td>70952000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable organ fixation pelotte</td>
<td>A device that is used to fix or maintain the organ in situ during a procedure or examination. This device is reusable.</td>
<td>70953000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic surgical spatula</td>
<td>A surgical device in spatulated shape usually made of stainless steel, and used to apply a drug onto the surface of the eye, treat the ocular tissue, and remove substances from the surface of the eye and surrounding structures. Some have a handle at the proximal end, and a flat blade without sharp angles at the distal end. Some shaft or blade is straight, some is curved or bent at various angles from the handle to the distal end.</td>
<td>32754001</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT surgical probe</td>
<td>A surgical probe that is made of flexible metal, has a ball-like or a pointed thin, long stick-like end. Used to search for a fistula, cavity or wound during otorhinological treatment. Some have a distal end before the ball or sharp point that bend forming a right angle</td>
<td>33433000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Eye brush</td>
<td>A brush used to collect tissue samples, or apply drugs onto the surface of the eye or related structures. Some have a handle on one end, and bristles, fibers, or spikes on the other end. Bristles, fibers, or spikes are inserted evenly in a plane surface, or radially around the axis. The shaft handle is flexible or rigid, and bristles are soft or hard.</td>
<td>34880000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Evisceration prosthesis</td>
<td>A device that is used to hold or fix the abdominal organs in situ.</td>
<td>35654000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Gynaecological dissector</td>
<td>A device that is used to collect mucosal tissue from the uterus for cytological diagnosis. This device is for single-use.</td>
<td>70955000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Instrument Name</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Status</td>
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<tr>
<td>Surgical drill handpiece</td>
<td>This manual or power-operated (e.g., air, nitrogen, battery, power source) device is used on its own, or used as a motor-driven device equipped with various attachments (e.g., chuck, reaming attachment, wire inserter/guide, percussor). Some can be cannulated so as to be used over a guide wire. It adopts either a micro or macro design. It can be used in procedures such as limb lengthening for patients with legs of different lengths. For the lengthening, the device is usually connected to the bone with pins. External fixation may be used. Some are used for spinal fusion or maxillofacial surgery.</td>
<td>37146000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Distractor</td>
<td>A surgical device used to separate connected surfaces, and to retain their positions to allow a surgical operation to be performed. Some are used for long bones in lengthening procedures (limb lengthening for patients with legs of different lengths). For the lengthening, the device is usually connected to the bone with pins. External fixation may be used. Some are used for spinal fusion or maxillofacial surgery.</td>
<td>11291000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bone tap</td>
<td>A metal surgical device that is used to cut threads on the bone surface in order to apply bone screws. The bone screws fix the bone fragments, fixture or other device to the bone.</td>
<td>17507000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bone mill</td>
<td>A mill used to crush the bone into slurry or powder which is used as bone matrix for bone regeneration or bone transplantation.</td>
<td>18129000</td>
<td>I</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bone screw starter</td>
<td>A surgical device that is used to start the insertion of the bone screw into the bone. It cuts the bone to form a desired angle to which the bone screw can be applied tightly or loosely.</td>
<td>32859000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical drill bit guide</td>
<td>A hand-held surgical device used to determine the position and angle of the drill hole, and protect the surrounding tissues. This is inserted into a tube so as to fit the dedicated drill bit size. It has a saw-like configuration at the distal end so as to secure stable fixation to an artificial joint, or other devices in order to fix the bone fracture.</td>
<td>35095000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic reamer</td>
<td>A manual orthopaedic device used to cut and expand the marrow cavity before inserting an artificial joint, or other devices in order to fix the bone fracture.</td>
<td>35297001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Manual orthopaedic cement dispenser</td>
<td>A manually operated injection syringe-like device used to inject orthopaedic (bone) cement into a surgical site. “Orthopaedic injectors” are excluded.</td>
<td>35809001</td>
<td>I</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable bone setting instrument</td>
<td>A surgical device used to connect bones in orthopaedic surgery, and refer to the manual bone drill, calcaneus compressor and innominate bone clasp. It is manually operated. This device is reusable.</td>
<td>70958001</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Countersink</td>
<td>A rotary surgical device used to expand the outer diameter of the drill hole to prevent the screw or bolt head protruding from the surface.</td>
<td>16462000</td>
<td>I</td>
<td>6-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Shaver system</td>
<td>A special system or a device used for percutaneous surgery of the joints (e.g., knee joint, shoulder joint). Some systems are exclusively used for other sites (e.g., nasal cavity). Usually used in conjunction with a dedicated endoscope so that the operator can have a visual view of the surgical site.</td>
<td>36436000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Gas-powered surgical drill handpiece</td>
<td>A drill consists of a single handpiece that includes a chuck which is used in combination with a drill bit, bone tap or wire. Some have a hollow structure into which a guide wire can be inserted. It adopts either a micro or macro design. It has a system powered by compressed air and compressed nitrogen can be used as a power source.</td>
<td>37876000</td>
<td>I</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Pneumatic bone operating instrument</td>
<td>A pneumatic surgical device used for bone surgery.</td>
<td>70960000</td>
<td>I</td>
<td>6-1</td>
<td>applicable</td>
</tr>
<tr>
<td>Bone staple driver</td>
<td>A hand-held surgical device designed to provide force to other devices to facilitate the insertion of a bone staple into tissue. The distal end has a configuration to be connected to a device which is to be inserted into the tissue. The proximal end is designed to absorb and transmit the impact.</td>
<td>10458000</td>
<td>I</td>
<td>6-1</td>
<td>N/A</td>
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<tr>
<td>Description</td>
<td>Code</td>
<td>Suffix</td>
<td>Remarks</td>
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<tr>
<td>Driver/extractor</td>
<td>A surgical device used in combination with other devices when inserting or removing pins, screws or other devices during surgery.</td>
<td></td>
<td></td>
<td>32390000</td>
<td>1</td>
</tr>
<tr>
<td>Reusable surgical drill bit</td>
<td>A drill bit connected to a manual or powered surgical perforator. With an appropriate rate of revolution, it produces a hole in the bone having the same diameter as itself. Usually, it is a “twist drill” type (spiral type). Some have a flat, angled blade. This device is reusable.</td>
<td></td>
<td></td>
<td>32865000</td>
<td>1</td>
</tr>
<tr>
<td>Prosthesis driver</td>
<td>A hand-held surgical device designed to provide force to other devices to allow an orthopaedic prosthesis to be inserted into tissue. The distal end has a configuration to be connected to a device which is to be inserted into the tissue. The proximal end is designed</td>
<td></td>
<td></td>
<td>32871000</td>
<td>1</td>
</tr>
<tr>
<td>Surgical wrench</td>
<td>A manually operated surgical device that has a fixed mating part, and is used to hold, turn or twist the nuts, bolts, and wire.</td>
<td></td>
<td></td>
<td>32878000</td>
<td>1</td>
</tr>
<tr>
<td>Acetabular socket pusher</td>
<td>A rod-like surgical device that has a grip and is designed to hold the acetabular cup or shell at the distal end. By using the socket pusher, the acetabulum of a hip prosthesis is inserted into an appropriate position in the acetabular roof of the pelvis.</td>
<td></td>
<td></td>
<td>32879000</td>
<td>1</td>
</tr>
<tr>
<td>Wire crimper</td>
<td>A manual orthopedic device, which has similar functions to the wire pressing forceps, that is used to bend a wire or fastener.</td>
<td></td>
<td></td>
<td>33968000</td>
<td>1</td>
</tr>
<tr>
<td>Surgical screwdriver</td>
<td>A surgical device has a shaft, and is designed to fit the screw threads so as to tighten or loosen the screw at one end by using torque. The head has either a single slot, cross slot, Phillips, Allen or hexagram configuration etc. The other end of the shaft is equipped with</td>
<td></td>
<td></td>
<td>34949000</td>
<td>1</td>
</tr>
<tr>
<td>Surgical bone clamp</td>
<td>A surgical device used to hold the bone, or connect the proximal or distal end of the fractured bone during surgery.</td>
<td></td>
<td></td>
<td>35090000</td>
<td>1</td>
</tr>
<tr>
<td>Surgical gouge</td>
<td>A heavy surgical device made of stainless steel, and used to resect bone and other hard tissue. It has a handle at the proximal end which is connected to a shaft. The distal end has a sharp, semi-circular configuration that ensures easy resection of tissue.</td>
<td></td>
<td></td>
<td>35166000</td>
<td>1</td>
</tr>
<tr>
<td>Intramedullary nail driver</td>
<td>A hand-held surgical device designed to provide force to other devices in order to insert an intramedullary rod into the tissue. The distal end has a configuration to be connected to a device which is to be inserted into the tissue. The proximal end is designed to absorb and</td>
<td></td>
<td></td>
<td>35589001</td>
<td>1</td>
</tr>
<tr>
<td>Reusable intramedullary canal cleaning brush</td>
<td>A brush used to remove blood clots and bone fragments from the medullary canal before injecting orthopaedic cement. Usually, it has a handle on one end, and bristles, fibers, or spikes on the other end. Bristles, fibers, or spikes are inserted evenly in a plane surface, or radially around the axis. The shaft handle is flexible or rigid, and bristles can be soft or hard. This device is reusable.</td>
<td></td>
<td></td>
<td>35647001</td>
<td>1</td>
</tr>
<tr>
<td>Reusable external fixation system</td>
<td>A special surgical system that consists of a case and several trays. The system is designed to be used for specific surgery such as bone fracture surgery, spinal surgery and orthodontic surgery. The external fixtures of this system can be reused in accordance with</td>
<td></td>
<td></td>
<td>35788000</td>
<td>1</td>
</tr>
<tr>
<td>Orthopaedic caliper</td>
<td>A surgical measuring instrument that consists of 2 legs connected by a hinge to one shaft. Used to measure the diameter and length of the bone.</td>
<td></td>
<td></td>
<td>36135000</td>
<td>1</td>
</tr>
<tr>
<td>Prosthetic joint facsimile</td>
<td>Copies of artificial joint components used to determine the size of the permanent artificial joint, or confirm that the part to be implanted has appropriate dimensions. (Trial components used for other types of orthopaedic surgery are included in this category.)</td>
<td></td>
<td></td>
<td>359/367</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Description</td>
<td>Code</td>
<td>Quantity</td>
<td>Status</td>
<td>N/A 1</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Orthopaedic file</td>
<td>A surgical device designed as a long, tapered trimming device with teeth which make holes in the bone tissue, and expand the holes.</td>
<td>36167001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Manually-operated surgical drill handpiece</td>
<td>A device consists of a manual handpiece including a chuck which is used with a drill bit, bone tap or wire. It is also known as a fixator or a bit. Some are inserted into a tube so that a guide wire can be inserted.</td>
<td>36235001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic bur</td>
<td>A small rotary shaft made of steel or other hard metal. It has a grooved surfaces or cut surfaces of various configurations on one end. Used for boring and forming of the bone tissue during maxillofacial surgery, spinal surgery and other bone surgery procedures.</td>
<td>36249001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable surgical drill attachment</td>
<td>This device is connected to a manual, electric or pneumatic handpiece, and used for specific tasks, drilling, reaming, severing and trimming, introducing and guiding the wire. Some have a decelerating gear to achieve the desired speed for specific operations. Some</td>
<td>37870001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Surgical crown drill bit</td>
<td>A hollow boring device used as a crown (crown type) drill or hollow mill. Before removing the screw that has lost its screw head, it is used for overdrilling the part including the shaft, and is also used to collect a sample from the center of the bone for biopsy.</td>
<td>37871001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable extention fixator</td>
<td>A fixator used to fix the pins, etc. inserted into bone or soft tissue for bone fracture treatment or bone lengthening out side the body. Usually, this device is reusable.</td>
<td>70961000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable instrument for bone surgery</td>
<td>A surgical device used for bone surgery such as osteosynthesis. The device is manually operated. This device is reusable.</td>
<td>70962001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable instrument for spinal surgery</td>
<td>A surgical device used for spinal fusion and the other spinal surgeries. The device is manually operated. This device is reusable</td>
<td>70963001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable joint operating instrument</td>
<td>A surgical device used for artificial joint replacement and other joint surgery procedures. Manually operated devices only. This device is reusable.</td>
<td>70964001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable dental implant surgical instrument</td>
<td>A surgical hand-held instrument used for dental implants and other surgical procedures. Manually operated. Some are used non-invasively. This device is reusable.</td>
<td>70965001</td>
<td>1</td>
<td>1,6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ligament/tendon reconstruction instrument</td>
<td>A stainless steel surgical device used to produce tunnels along the ligament or tendon tissue to produce connected channels. Usually, it is a flexible or hard rod that has a tapered handle towards the rod. It has a button or an acorn-shaped knob at the distal end. Some have the pivot near the distal end or ring handles with slightly curved long blades.</td>
<td>34827000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Ligament/tendon operating instrument</td>
<td>A surgical device used for ligament reconstruction and other forms of ligament and tendon surgery. Manually operated devices only.</td>
<td>70966001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable orthopaedic implant extractor</td>
<td>A surgical device used to remove a hip prosthesis, intramedullary rods and other orthopaedic implants. This device is reusable.</td>
<td>12696000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Item Name</td>
<td>Description</td>
<td>Code</td>
<td>Quantity</td>
<td>Unit</td>
<td>Comment</td>
</tr>
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</tr>
<tr>
<td>Surgical depth gauge</td>
<td>A depth measuring instrument used to measure the length of a screw used to tighten the edges of bone fracture, determine the appropriate length, and for many other medical purposes.</td>
<td>32845000</td>
<td>1</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic fixation forceps</td>
<td>Surgical forceps have specifically designed blades, and are used to hold an orthopaedic implant or device. Used by a surgeon or the operator for implanting a prosthesis to handle it safely during surgery.</td>
<td>42894000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Temporal bone holder</td>
<td>A bone holder for a surgical use to clamp and hold the bone fragments from the outside the surgical field so as to assist the operator and assistant. Used for bone reconstruction and production of graft materials. It has sturdy legs. Some have a dish-like structure to</td>
<td>43956000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Awl</td>
<td>A manual orthopaedic surgical device has a spike-like configuration, and has no blade. Used to make holes in the bone.</td>
<td>15275000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Bone skid</td>
<td>A long flat surgical device has a cradle at both ends. The cradles are formed to fit the outline of a specific bone. The skid is designed to slide under a specific region of the bone so that the bone can be moved, and the position can be decided.</td>
<td>32882000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic tape</td>
<td>A fabric or plastic (adhesive) tape used to fix a catheter, IV tube and other medical devices. (Tapes used for secondary fixation are excluded.)</td>
<td>32882000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic cerclage applier</td>
<td>A surgical device used to arrange, fix and connect an orthopaedic fastening loop, clamp or wire.</td>
<td>35797000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Orthopaedic cement extractor</td>
<td>A device or a set of devices used to remove orthopaedic (bone) cement from the affected site. It may include a “slap hammer” used to crush bone cement, a chisel (electric or manually-operated orthopaedic cement extractor) used to remove orthopaedic (bone) cement from the affected site when replacing an artificial joint fixed with cement. The group of these general devices may include the “slap hammer” used to crush bone cement for removal, a chisel or other manual instruments.</td>
<td>37065009</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Dermatome skin approximation tape</td>
<td>A tape that comes in various sizes with adhesive on both sides. It is attached onto a skin graft knife to collect a skin graft tissue. This device is for single-use.</td>
<td>70967000</td>
<td>1</td>
<td>2</td>
<td>applicable</td>
</tr>
<tr>
<td>Vaginoplasty instrument</td>
<td>A device that is inserted into the abdominal cavity in order to prevent the restenosis of the abdominal cavity for patients who do not have a vagina after construction of the vagina by skin valve transplantation use of the peritoneum or other procedures (e.g. use of sigmoid)</td>
<td>70968000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Hammer</td>
<td>A metal (Usually stainless steel) device that consists of a handle, shaft and head. The handle is usually round, and designed to fit into the palm. The handle is tapered towards the shaft. The head is placed at the end of this shaft usually with cylindrical shape, but</td>
<td>11947010</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Wooden hammer</td>
<td>A wooden hammer.</td>
<td>11947020</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Spatula</td>
<td>A spatula usually made of stainless steel, and used to apply a drug to the surface, fill drugs into a cavity, treat the tissue, and remove substances from the surface or blood vessels. It has a handle at the proximal end, and a flat blade without a sharp angle at the distal end. The shaft or blade is straight or bent in various angles from the handle.</td>
<td>13645000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dilator</td>
<td>A surgical device that is used to dilate the inner diameter (caliber) of an orifice, lumens or blood vessels.</td>
<td>11254000</td>
<td>1</td>
<td>6-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Nasal dilator</td>
<td>A flexible, thin cylindrical, hollow or rod-like device made of metal or plastic, and that comes in various sizes. Used to dilate the nasal structure and nasal cavity.</td>
<td>11260000</td>
<td>1</td>
<td>5-1</td>
<td>N/A</td>
</tr>
<tr>
<td>Description</td>
<td>Definition</td>
<td>Code</td>
<td>Function</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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</tr>
<tr>
<td>Rectal dilator</td>
<td>A device used to dilate the anal sphincter and anus to allow the smooth insertion of a device for examination of anal function.</td>
<td>11262000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Tracheal dilator</td>
<td>A flexible, thin cylindrical, hollow or rod-like device that is made of metal or plastic, and comes in various sizes. Used to dilate the tracheal structure and tracheal passageway.</td>
<td>11263000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable urinary duct dilator</td>
<td>A flexible, thin cylindrical, hollow or rod-like device that is made of metal or plastic with various sizes. Some have a mechanism to dilate the urethra and its degree is indicated on the dial. This device is reusable.</td>
<td>11265000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Vaginal dilator</td>
<td>A device that is inserted into the vagina, and placed there for a certain period. The insertion part has a round end for smooth insertion. It is used to dilate a narrow vaginal opening due to a congenital defect. It may interfere with sexual conduct.</td>
<td>11267000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable urethral bougie</td>
<td>A flexible, cylindrical, hollow or solid device that is used to diagnose urethral stenosis. It is made of metal or plastic and comes in various diameters. This device is reusable.</td>
<td>14286000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Esophageal dilator</td>
<td>A thin hollow or solid cylindrical device (usually, a surgical device) is made of iron, plastic, or other appropriate materials, and comes in various sizes and flexibilities. Used to dilate the esophageal structure and passageway.</td>
<td>35009000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Lachrymal eye dilator</td>
<td>An ophthalmic device used to dilate the lacrimal punctum.</td>
<td>35010000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>ENT bougie</td>
<td>A rod-type surgical device used to examine or dilate a stenosis during otologic surgery.</td>
<td>35022000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Esophageal bougie</td>
<td>A hollow cylindrical surgical device with an olive-shaped metal weight. It slides over a string or wire guide, and is used to dilate an esophageal stenosis. (Some are made of tapered plastic.)</td>
<td>35052000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable medical dilator</td>
<td>A device used for dilation. Electrical devices are excluded. This device is reusable.</td>
<td>70969001</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Applicator for medical use</td>
<td>A device used to apply drugs on the body or in the body, perform treatment, collect samples for examination, or clean the apparatus place in the body by a method that has possibility to contact the body tissue. The applicator comes in various types, each of which usually has a specific function: 1. A simple thin rod made of wood, flexible metal or synthetic fiber molded into a stick shape.</td>
<td>10172000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Eye applicator</td>
<td>A thin ophthalmic rod made of wood, flexible metal or synthetic material with lint or synthetic fiber at one end. Some have a sponge-like absorber made of lint or synthetic fiber molded into a stick shape.</td>
<td>10175000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Single-use laryngotracheal topical anesthesia applicator</td>
<td>A thin stick used to apply local anesthesia to the larynx and trachea. This item is for single-use.</td>
<td>31343000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-sterile absorbent tipped applicator</td>
<td>A thin, long stick made of wood, flexible metal or synthetic material with a non-sterile absorber at one end. It is used to absorb a material from any accessible surface and internal area of the body. Sometimes, the absorbed material is used as a sample for superficial tissue foreign body extraction.</td>
<td>33721000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile absorbent tipped applicator</td>
<td>A thin, long stick that is made of wood, flexible metal or synthetic material with a sterilized absorber at one end. It is used to absorb a material from any accessible surface and internal area of the body. Sometimes, the absorbed material is used as a sample for superficial tissue foreign body extraction.</td>
<td>33722000</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
</tr>
<tr>
<td>Superficial tissue foreign body extractor</td>
<td>A magnetic or mechanical forceps used to remove foreign matter from the skin, superficial fascia, and other superficial tissue for minimizing tissue injury.</td>
<td>15580000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Equipment</td>
<td>Description</td>
<td>Code</td>
<td>Class</td>
<td>Category</td>
<td>Notes</td>
</tr>
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</tr>
<tr>
<td>Eyes spud</td>
<td>A thin, long, probe-like device used to catch and remove foreign matter from the ocular surface.</td>
<td>16025000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Cerebral surgery mirror</td>
<td>A neurosurgical device used to observe the surgical site during neurosurgery. Inserted through a surgical opening of the cranial. Usually, it consists of a mirror, shaft, and handle.</td>
<td>70970000</td>
<td>1</td>
<td>6-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Gastrointestinal sizer</td>
<td>A device used to measure the size of a digestive organ. Some measure the size of the lumen, and others measure the depth of a fistula.</td>
<td>70971000</td>
<td>1</td>
<td>5-①</td>
<td>N/A</td>
</tr>
<tr>
<td>Spectacles</td>
<td>A device that consists of a pair of lenses and a frame to hold the lenses.</td>
<td>35065000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>High magnification lens system</td>
<td>A lens system used for visual magnification of patients with a visual disorder. It comes in a scope for distant or near view, or a magnifying lens for near view.</td>
<td>30047000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Tinted lens</td>
<td>A lens that weakens radiated light by its absorption or reflection.</td>
<td>30048000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Spectacle lens</td>
<td>A glass or plastic device used to correct a refraction error of the eye according to a prescription, or protect the eyes from radiation and mechanical hazard. Some are worn on top of the eye glasses for its protection.</td>
<td>35957000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Eikonometer</td>
<td>An ophthalmic device used to diagnose aniseikonia.</td>
<td>11391000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Tachistoscope</td>
<td>An ophthalmic device used to illuminate letters and images at various speeds for ophthalmic diagnosis and examination.</td>
<td>13970000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Nystagmus inducing optokinetic drum</td>
<td>A drum-like ophthalmic device covered with black and white strips or patterns. Used to induce and assess nystagmus (involuntary rapid eyeball movement).</td>
<td>16476000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Visual acuity eye chart</td>
<td>A visual acuity chart used to test visual acuity. Some have a visual target inside a box with the background illuminated and a letter or symbol is selectively shown.</td>
<td>16800000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Amsler chart</td>
<td>An ophthalmic device used to detect disorders in the center or near-center of the visual field. Some are a series of charts with a grid in various sizes, and placed at a distance of 30 cm from the patient.</td>
<td>32786000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Visual acuity projector</td>
<td>A projection-type examination device for testing visual acuity and visual sense. Some use black letters or other symbols which are reduced step wise according to the distance, and projected on the screen or wall to test visual acuity.</td>
<td>35922000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Polatest</td>
<td>A device used to assess latent strabismus. When the patient does not recognize it, and it cannot be confirmed visually, the visual target that is polarized by the phoropter cannot be recognized as a proper cross shape by the patient. The phoropter is adjusted until the</td>
<td>37070000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Visual acuity testing equipment</td>
<td>A visual acuity test apparatus that presents optically far or near visual targets.</td>
<td>70973000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Name</td>
<td>Description</td>
<td>Code</td>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>Ophthalmoleukoscope</td>
<td>A color perception test device that uses polarized light.</td>
<td>12810000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Colour discrimination tester</td>
<td>A color perception test device that uses color threads or color perception plates. Color perception is assessed using an ophthalmic device that consists of various color materials such as multi-color plates, which are perceived as one color by patients with defective color vision.</td>
<td>32687000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Colour discrimination chart</td>
<td>An ophthalmic chart that consists of color patterns printed on a colored (including white) background. Used for a color perception test.</td>
<td>35898000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Colour discrimination quick-test</td>
<td>A color perception test device used to rapidly assess the ability to recognize various colors. Used for pilots and sailors. It consists of one or several disks. Some have colored glasses which can be manually replaced, and are used to indicate a selected color. The patient</td>
<td>37066000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Fresnel lens</td>
<td>A thin flexible ophthalmic lens or prism that is worn temporarily on top of the lenses of eye glasses, usually for the purpose of diagnosis.</td>
<td>32693000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Prism bar</td>
<td>A device that consists of prisms having various reflective indexes, and is used to assess the function of the ocular muscles during a visual acuity test.</td>
<td>32719000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Trial lens frame</td>
<td>A lens frame that is used to hold the trial lens in front of the eye during a refraction test.</td>
<td>32791000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmic spectacle clip</td>
<td>A clip used to hold a prism, spherical, cylindrical piece or shield on a trial glass frame or glass frame during a visual acuity test.</td>
<td>32792000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Trial lens</td>
<td>A lens that is used for optometry.</td>
<td>34653000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Manual pupillometer</td>
<td>A manual ophthalmic device used to measure the width and diameter of the pupil. In order to assess the pupil, the diameter and other measured values of the pupil relative to the parameters of the device are measured.</td>
<td>32727000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Ophthalmodiastimeter</td>
<td>A device used to measure the distance between the eyes in order to fit prescribed lenses properly.</td>
<td>12805000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Pupillometer</td>
<td>An ophthalmic device used to measure the width and diameter of the pupil.</td>
<td>13236000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Pachometer</td>
<td>A device used to measure the thickness of the cornea using an optical technique.</td>
<td>1633001</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Exophthalmometer</td>
<td>An ophthalmic device used to measure the degree of abnormal protrusion of the eyeball.</td>
<td>16345000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>Haidinger brush</td>
<td>An apparatus (usually, having an AC power source) creates the image of 2 conical brushes connected at their tops. Some are used to examine the visual function and the function of the macula lutea by showing an image through a Nicol prism.</td>
<td>32688000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Extracorporeal eyelid weight</strong></td>
<td>An ophthalmic device used to place a weight on the upper eyelid, or compress the eyelid in order to restore its function. Some are worn on the outside of the upper eyelid so as to place a load (place a force on the eyelid). It is also used to treat transient paralysis, or measure the size of an eyelid weight to be implanted before surgery.</td>
<td>18142000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td><strong>Recumbent spectacles</strong></td>
<td>Prism eyeglasses used by bed-ridden patients so they can read books in the supine position.</td>
<td>30143000</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Ocular pressure applicator</strong></td>
<td>A device used to apply pressure on the eye during ophthalmic surgery. Some are a manual apparatus that has a valve that compresses the site just like a sphygmomanometer. Some are equipped with a dial gauge, band and bellows.</td>
<td>33804000</td>
<td>1</td>
<td>6①</td>
<td>applicable</td>
</tr>
<tr>
<td><strong>Cotton ball</strong></td>
<td>A cotton ball used to apply drugs to the various site of body or wipe off liquid.</td>
<td>11028000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Eye pad</strong></td>
<td>A pad made of gauze, cotton or various other materials. Used to protect the eye or absorb secretions.</td>
<td>11661000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Gauze sponge</strong></td>
<td>A gauze that is intended to apply to surgical incisions and other skin wounds or an internal structure in order to stop bleeding, absorb liquid, and protect the organs from abrasion, dryness, or contamination.</td>
<td>13700000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>X-ray detectable sponge</strong></td>
<td>A sponge that contains an X-ray detectable agent, and is intended to apply to surgical incisions and other skin wounds or an internal structure in order to stop bleeding, absorb liquid, and protect the organs from abrasion, dryness, or contamination.</td>
<td>13705000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Laparotomy sponge</strong></td>
<td>A sponge used inside the body during laparotomy in order to stop bleeding, absorb liquid, and protect the organs from abrasion.</td>
<td>15085000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>X-ray detectable gauze</strong></td>
<td>A cotton or cellulose absorbent does not contain any drug, and is used inside the body or for surgical incisions in order to stop bleeding, absorb liquid, and protect the organ from abrasion, dryness or contamination.</td>
<td>32374000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Cottonoid pad</strong></td>
<td>A pad made from cotton or synthetic fiber, used during surgery in order to protect nerve tissues, absorb liquid, or hemostasis.</td>
<td>32572000</td>
<td>1</td>
<td>4③</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Non-woven gauze</strong></td>
<td>A cover/protection material made of non - woven fabric, and used to treat wounds or surgical incisions.</td>
<td>34655000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Medical absorbent cotton</strong></td>
<td>A medical pad, is made from cotton fiber, used to apply drugs, absorb a small amount of body fluid from the body surface, or for other medical purposes</td>
<td>70975000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Medical sponge</strong></td>
<td>A sponge made of a polymeric material, and used to apply drugs to various body parts, or remove liquid. Wound cover and protection materials are excluded.</td>
<td>13695000</td>
<td>1</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Latex sheet drape with self-retaining finger cot</strong></td>
<td>A latex cover with self-retaining finger cot. The surgeon wears it when he/she inserts his/her finger into the rectum during transurethral prostatectomy.</td>
<td>31978000</td>
<td>1</td>
<td>5①</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Description</td>
<td>Code</td>
<td>CTE Qty</td>
<td>CTE Unit</td>
<td>Other Remarks</td>
<td></td>
</tr>
<tr>
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<td>----------</td>
<td>---------</td>
<td>----------</td>
<td>-------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Single-use finger protector</td>
<td>35073000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Reusable finger protector</td>
<td>42050000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Non-latex medical examination glove</td>
<td>70976000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Latex medical examination glove</td>
<td>70977000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Hernia aid strap</td>
<td>30883000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Hernia aid girdle</td>
<td>30884000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Infant hernia aid strap</td>
<td>35409000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Home use low frequency therapy electrode</td>
<td>71008000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Home use electric potential therapy apparatus electrode</td>
<td>71009000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Home use hot pack</td>
<td>71019000</td>
<td>1</td>
<td>N/A</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Menstrual tampon</td>
<td>35694000</td>
<td>1</td>
<td>5③</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Adhesive bandage</td>
<td>34864000</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Liquid bandage</td>
<td>33584000</td>
<td>1</td>
<td>4</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Home use contact granule patch</td>
<td>71026000</td>
<td>1</td>
<td>1</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Home use noninvasive acupuncture equipment</td>
<td>34675001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Mass spectrometric analyzer</td>
<td>57848001</td>
<td>1</td>
<td></td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Storage and display device for pathological whole slide image</td>
<td>15132021</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>I</td>
<td>1</td>
<td>applicable</td>
<td>367/367</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----</td>
<td>----</td>
<td>------------</td>
<td>---------</td>
</tr>
<tr>
<td>External pacemaker cable or adaptor</td>
<td>A cable or adaptor used to connect cardiac electrodes and external pacemaker which are used for temporary pacing, and transmit a stimulating electric current to the heart and action potential signals of the heart.</td>
<td>71061001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Electronic tourniquet</td>
<td>An electronic device used to pressurize the upper and lower extremities for avascularization. It is used to overswell the vein for puncturing. The cuff pressurizes automatically.</td>
<td>71063001</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Intra-vaginal organ positioning device for diagnostic imaging and radiotherapy</td>
<td>A device that is specifically designed to be inserted in the vagina to properly position and fix the surrounding organs such as uterine cervix, rectum, and urinary bladder for image diagnosis or radiotherapy. This device is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.</td>
<td>71067001</td>
<td>1</td>
<td>5&lt;sup&gt;①&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>3D organ phantom</td>
<td>A model reproducing the individual patient's actual organ structures based on his/her imaging data such as CT and MRI. It is complimentarily used for medical treatment with other diagnostic information, as a purpose of confirmation of the organ structure, etc.</td>
<td>62215001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Dry pasteurization device</td>
<td>A warming device that is small, and usually heats to no less than 62°C for at least 30 minutes without use of warm water, and kills almost all infectants. This method is indicated only for the cases that do not need complete sterilization.</td>
<td>71069001</td>
<td>1</td>
<td>12</td>
<td>N/A</td>
</tr>
<tr>
<td>Erythrocyte sedimentation rate measuring instrument</td>
<td>A device that manually measures the rate of erythrocyte sedimentation (sinking), which is known as the erythrocyte sedimentation rate (ESR), in whole blood samples.</td>
<td>55974001</td>
<td>1</td>
<td>—</td>
<td>N/A</td>
</tr>
<tr>
<td>Oral/swallowing function exerciser</td>
<td>A non-active device used under the instruction of a doctor, etc. for rehabilitation of deterioration in oral or swallowing functions.</td>
<td>63278001</td>
<td>1</td>
<td>5&lt;sup&gt;①&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Reusable drainage flowmeter</td>
<td>A device that directly or indirectly measures the amount of drainage from the thoracic or abdominal cavity when it is connected with the thoracic or abdominal cavity drain. Measurement is mechanical, electrical or a combination of both. This is reusable use.</td>
<td>71071001</td>
<td>1</td>
<td>12</td>
<td>applicable</td>
</tr>
<tr>
<td>Surgery instrument for root canal treatment</td>
<td>A surgical instrument used for root canal treatment. Manually operated. Some are used non-invasively. This device is reusable.</td>
<td>71074001</td>
<td>1</td>
<td>1&lt;sup&gt;①&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Sizer for valvuloplasty</td>
<td>A surgical device manually operated during valve reconstruction and valvuloplasty. It can measure the size of the valve cusp for heart valve surgery using autologous pericardium, etc. of the appropriate size. Some include handle used in sizer and holder. This device is reusable.</td>
<td>47684001</td>
<td>1</td>
<td>6&lt;sup&gt;①&lt;/sup&gt;</td>
<td>N/A</td>
</tr>
<tr>
<td>Motorless fixed-aperture accelerator system collimator</td>
<td>Fixed-aperture collimator assembly that is not equipped with a motor. It is positioned between the subject and the beam projection port of the accelerator's collimator housing and is used to adjust the form of the radiation beam that is delivered to the therapeutic target area of the body. It is made of a highly attenuating material or alloy including lead or tungsten, and protects patients by controlling or avoiding delivery of radiation to non-target area of the body.</td>
<td>42265001</td>
<td>1</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>Microbial quantitative analyser</td>
<td>An automatic or semiautomatic device that uses electrical impedance to quantify microorganisms in biological samples. For example, it is used to quantify microorganisms in samples collected from the oral cavity for examination.</td>
<td>71086001</td>
<td>1</td>
<td>—</td>
<td>applicable</td>
</tr>
</tbody>
</table>