Provisional Translation (as of June 2024)
This English version of the Japanese review point is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Review Point for Supporting Software for Dental Implant Treatment

Pharmaceuticals and Medical Devices Agency (PMDA)
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Introduction

At the time of making an approval application, information on the review point will be organized and released from medical device programs that have been approved after 2014.

- This review point shall indicate necessary endpoints, etc. for medical devices shown in the specified scope to contribute to the improvement of efficiency in preparation of materials and acceleration of reviews for an approval application.
- This review point shows the concept of review based on the current scientific knowledge, and it shall be reviewed and revised as needed according to future advances in science and technology.

1. Scope of Application

This review point applies to the programs aimed at supporting dental implant treatment planning and designing/manufacturing surgical guide plates among the supporting software for dental implant treatment specified in No. 1963 of the Appendix 2 of specially controlled medical devices, controlled medical devices, and general medical devices designated by the Minister of Health, Labour and Welfare according to the stipulations in Article 2, Paragraphs 5 to 7 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHLW Ministerial Announcement No. 298 of 2004).

2. Endpoints

Medical devices falling under the scope of application shall be evaluated with reference to the items shown in 2.1 to 2.7 below. If another evaluation method is used, its validity shall be explained.

If the device has a function to present an appropriate draft dental implant treatment plan and a draft surgical guide plate design, it shall be noted that new evaluation is required because the evaluation is insufficient with only the items shown in 2.1 to 2.7.

Even for devices falling under the scope of application, if there is novelty in any of the intended use or effects, shape, structure and principle, and directions for use compared to already-approved medical devices, the novelty shall be appropriately evaluated.

2.1 Image input function obtained by X-ray CT or digital impression taking apparatus

Requirements for image information that can be input to the program (for example, identification of combined medical devices, imaging mode (optical impression, X-ray CT, X-ray, etc.), image resolution, etc.) shall be clarified.

When data are transferred directly from a concomitant medical device, clarify the combined medical device, the combined medical device, patient information and the means of receiving data in the program shall be clarified, and it shall be confirmed that the program can receive data appropriately.

1) Have requirements for input data defined to ensure the quality of the 3D images entered into the program.
2) It shall be evaluated that the performance related to design data output is secured within the range of the above input requirements.

2.2 Patient information display function

It shall be confirmed that the 3D image information of the patient entered in the program can be displayed.

2.3 Implant treatment planning function

It shall be confirmed that the type, number, position, direction, depth, etc. of dental implants to be inserted can be displayed. In addition, it shall be confirmed that the dental implant to be inserted can be displayed overlaid on the 3D image, etc. of the patient entered in the program.

2.4 An alert display function to prevent the implant to be inserted from overlapping with the anatomical structure

The positions of the nerves, blood vessels, nasal cavity, and maxillary sinus in the upper and lower jaws shall be grasped, and it shall be confirmed that the alert is displayed so that they do not overlap with the dental implant to be inserted.

2.5 Treatment planning and surgical guide plate design functions and treatment planning and design data output functions

2.5.1 Treatment planning and surgical guide plate design functions

It shall be confirmed that the patient image can be displayed, the components related to the implant body, abutment, and prosthesis can be displayed on the image, and that the operator can support simulation of the treatment plan and design of the surgical guide plate by indicating the presence or absence of mutual consistency and conflict.

2.5.2 Treatment planning change and surgical guide plate design change instruction functions

It shall be confirmed that the functions, change history, etc. such as instructing changes related to the treatment plan and surgical guide plate design on the screen operation and entering comments can be displayed.

2.5.3 Design approval function for treatment plan and surgical guide plate

The function to confirm the treatment plan and surgical guide plate design and to approve them if there is no change, etc. shall be confirmed.

2.5.4 Design data output function

Regarding the data of the treatment plan and the surgical guide plate design output from the medical device program, it shall be confirmed that the error with the surgical guide plate prepared based on the data is the preset precision with which clinical utility can be explained by comparison with the final product.

2.6 Image display function

It shall be confirmed that the treatment plan and surgical guide plate design prepared can be displayed as 3D images, etc.

2.7 Image information processing function

It shall be confirmed that the arithmetic processing function of the displayed images such as 3D images (image enlargement/reduction, movement and rotation of display, and superposition, etc.) can operate. In addition, it shall be confirmed that the measurement distance and measurement angle have the accuracy that can explain the clinical usefulness set in advance.

3. Points to Consider for Preparing Application Forms

Each column of the application form and submitted data shall be in accordance with "8. Handling of application for marketing approval" of “Handling of Medical Device Software” (Joint PFSB/MDRMPED Notification No. 1121-33, PFSB/SD Notification No. 1121-1, PFSB/CND Notification No. 1121-29, dated November 21, 2014, by the Counsellor of Minister’s Secretariat, Ministry of Health, Labour and Welfare (the Director of the Medical Device and Regenerative Medicine Evaluation Division), Director of the Safety Division of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, and the Director of the Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare), and "Notice concerning the Publication of Guidance Materials concerning Application for Marketing Approval of Medical Device Software” (Administrative Notice of the Office of Director of the Medical Device and Regenerative Medicine Evaluation Division, Pharmaceutical Safety and. Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated March 31, 2016).

In addition to the above, items considered to be particularly necessary shall be described with reference to the following items.

3.1 Directions for use column

The materials for the surgical guide plate to be designed, the method for creating the surgical guide plate, the equipment to be used and the combination conditions shall be identified.