Provisional Translation (as of June 2024)
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Review Point for Software for Ophthalmic Surgery Treatment Planning

Pharmaceuticals and Medical Devices Agency
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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 software for ophthalmic surgery treatment planning specified in No. 1115 of the Appendix 1 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).

- This document describes:
  - Input data: Data to be entered into the program for storage or processing.
  - Output data: Data to be transferred externally by the program.
  - Simulation: To perform data processing using this program in order to describe the selected operating characteristics of the physical or abstract system (e.g., corneal shape after laser treatment).
  - Treatment plan: All information related to patient and laser irradiation intended to be used by qualified persons for prescription or implementation of laser treatment. This also includes information transferred to the combined ophthalmic laser corneal surgical system.
  - Laser irradiation data: A set of pre-programmed laser irradiation and system movements that can automatically provide treatment in one patient setting. Specific examples of physical parameters related to laser irradiation include wavelength, pulse width, image size, laser irradiance, and laser radiant exposure. In addition, specific examples of parameters related to system movement include the scan range, coordinates, time, sequence, etc.

2. Endpoints

Medical devices falling under the scope of application shall be evaluated with reference to the items shown in 2.1 to 2.5 below. If another evaluation method is used, its validity shall be explained. It is not necessary to cover all items shown in 2.1 to 2.5, and the corresponding items shall be evaluated according to the functions of the medical device.

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.

If there is novelty or uniqueness and there is a principle, etc. to derive output data from input data (including treatment plans for new incision/excision methods), the necessity of clinical studies may be an issue. In order to evaluate the validity of treatment using simulation based on the derivation principle, it is necessary to make a judgment based on the treatment result.

2.1 Data reception function (when data are transferred directly from a combined medical device)

Information on the combined medical devices (e.g., refractometer, refractokeratometer, refractokeratometer/tonometer, corneal topography system) and their users ("patients") (including test results) and the means of receiving data in the program shall be clarified, and the program shall be able to receive data appropriately.

2.2 Simulation function

Postoperative corneal shape, corneal excision shape, corrected volume, excision diameter, excision depth, or residual corneal thickness (hereinafter referred to as "postoperative corneal shape, etc.") shall be output/displayed appropriately.

1) The process of deriving output data from input data shall be clarified. The development background of the derivation principle (based on the publicly known calculation method, independently developed, etc.) shall also be clarified.
2) When explaining the equivalence to the existing product by using the same function of simulating the postoperative corneal shape, etc. built in the existing approved ophthalmic corneal surgery laser system to be used in combination, it shall be explained that the algorithm is the same as that of the existing product. Specifically, it is necessary to show that the process of derivation of input/output items and postoperative corneal shape, etc. is the same as the existing product.
3) When the postoperative corneal shape, etc. output by the program is directly input to the combined ophthalmic corneal surgery laser system, etc., it is necessary to compare and evaluate the simulation results with the irradiation results based on the postoperative corneal shape, etc. shown by the program in order to confirm the validity of simulation. The comparative evaluation is detailed in Section 2.4.
4) If an abnormal value that cannot be calculated by the program is entered and/or if the eye area outside the range of the treatment plan is selected, the error display function (such as no calculation result is output) shall be evaluated.

2.3 Laser irradiation data creation function

The laser irradiation data to realize the intended corneal shape, etc. shall be created based on the pre-entered data.

1) The process of deriving laser irradiation data from simulation results shall be clarified.
2) When explaining the equivalence to the existing product by using the same function built in the ophthalmic corneal surgery laser system, it shall be explained that the algorithm is the same as that of the existing product. Specifically, it is necessary to show that the process of derivation from the input/output items and simulation results is the same as the existing product.
3) If the input/output items or the process of deriving the laser irradiation data is different

from the laser irradiation data creation function built in the ophthalmic laser corneal surgery device, it is necessary to show the results of simulation and the results of evaluation based on the laser irradiation data indicated by the program in order to confirm the validity of the derived laser irradiation data and the validity of simulation. The comparative evaluation is detailed in Section 2.4.

4) The specific items of the laser irradiation data output by the program include the position in a single pulse laser irradiation, beam diameter (spot size), irradiation time (including pulse width, frequency, irradiation frequency), irradiation output (energy of single laser irradiation), irradiation sequence, etc., but not limited to them. Instead of the beam diameter (spot size), parts mounted on an ophthalmic corneal surgery laser system, aperture/slit opening diameter, degree of opening/closing of the shutter, etc. may be specified.
5) In the process of creating laser irradiation data, it shall be confirmed that the excision range and irradiation sequence are considered to reduce the effects of heat accumulation, etc. due to laser irradiation.

2.4 Validation of simulation

The appropriateness of simulation shall be evaluated by comparing the simulation results and the results of excision with actual laser irradiation. The postoperative corneal shape, etc. by simulation and that after excision by laser irradiation shall be compared to show that the alignment is consistent (accuracy).

1) If the combined ophthalmic corneal surgery laser system is an excimer laser, an evaluation based only on the representative surgical technique (e.g., myopia correction LASIK with the maximum correction amount) may be acceptable if extrapolation to other surgical techniques included in the intended use of the combined laser system (e.g., myopia correction LASIK result can be extrapolated to hyperopia correction LASIK, PRK, and PTK in a program) can be explained. In this case, it is desirable to compare with the maximum correction amount (e.g. spherical equivalent 10.0 D).
2) If the combined ophthalmic corneal surgery laser system is a femtosecond laser, it shall be confirmed that the incision accuracy and flap creation accuracy secured by the system are equivalent or superior to those of the existing products even when the program is used.
3) It shall be verified that the alignment of the postoperative corneal shape, incision/excision method, etc. by simulation are consistent with that of the postoperative corneal shape, etc. by laser irradiation (accuracy) using a model test.

2.5 Data transmission function (when the laser irradiation data are directly transferred to the combined medical device)

It shall be evaluated that the parameters of the combined ophthalmic corneal surgery laser system, etc. can be set based on the laser irradiation data or correction amount output in the

program. At that time, the means and parameters that can be set for the combined ophthalmic corneal surgery laser system, etc. shall be clarified.

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 Intended use or effect column

1) The surgical procedures to which the program applies (e.g., laser *in situ* keratomileusis (LASIK): correction of myopia, myopic astigmatism, hyperopia, hyperopic astigmatism, etc., photorefractive keratectomy (PRK): correction of myopia, myopic astigmatism, etc., phototherapeutic keratectomy (PTK), arc-shaped incision, etc.) and the extent of excision (upper limit of refractivity (e.g. spherical equivalent 10.0 D)) shall be confirmed and identified.
2) It shall be limited to the surgical procedure and range specified for the combined ophthalmic corneal surgery laser system.

3.2 Shape, structure, and principle column

1) Input/output parameters shall be identified.
   a) Items to be entered/worked by physicians
   b) Items to be calculated/processed by the program
2) Algorithms (such as calculation formulas) for creating simulation (treatment plan) and/or laser irradiation data shall be specified.
3) The postoperative corneal shape, etc. or laser irradiation data calculated by the algorithm specified in 2) shall be specified.

3.3 Directions for use column

1) Requirements for the ophthalmic corneal surgery laser system (combined medical device) that provides treatment based on the calculation results (postoperative corneal shape, etc. or laser irradiation data) by the program shall be identified.

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