
Appendix 2

Technical Review Guideline for Registration of Medical X-ray Diagnostic Device (Class III) (2016 Revised Edition)

This guideline aims to help the applicants prepare and compose documents for their medical X-ray diagnostic device (Class III) registration and also provide a reference for the registration authorities to technically review the registration application documents.

This guideline defines the general requirements for medical X-ray diagnostic devices (Class III). The applicant should determine the applicability of the provisions in this guideline based on product features and explain the reason for any inapplicability as well as corresponding scientific basis. The applicant should also substantiate the registration application documents with detailed information based on specific product features.

This guideline serves as an instruction document for the applicant and review personnel, but it neither involves any administration procedures for registration approval nor acts as a compulsory regulation. Methods other than those mentioned in this guideline can also be used if they comply with relevant regulations, however, detailed research and verification material should be provided with such methods. This guideline should be used without violating any relevant regulations.

This guideline is established in the framework of current regulations and standards and based on current knowledge. As the regulations and standards keep on improving and technologies continue to evolve, the provisions of this guideline will be adjusted accordingly.

This guideline is the revised edition of *Technical Review Guideline for Registration of Medical X-ray Diagnostic Device (Class III) Products*, which was published by China Food and Drug Administration (CFDA) in 2010. This revision mainly involves: (1) Rearranging the sections

and chapters of the guideline according to *Announcement of CFDA about Publishing Medical Device Registration Declaration Data Requirement and Approved Documentary Evidence Format* (No. 43 order, 2014). (2) Revising the scope of the guideline. (3) Changing the section name from "Original Technical Data" to "Summary Information". (4) Adding detailed requirements in Research Information. (5) Revising relevant requirements according to *Principles of Technical Guidance on Medical Device Clinical Evaluation*. (6) Adding the requirements for interventional devices used in clinical trials (7) Adding the content of Technical Requirement of Product (8) Revising the requirements of Product Registration Unit Classification

I. Scope

This guideline applies to medical angiography X-ray device, X-ray fluoroscopy radiography system (Class III) and mobile C-arm X-ray device (Class III). The classification code of the product is 6830.

II Comprehensive information

(I) Description of working principle

The description of working principle and the schematic diagram of X-ray device should be provided.

(II) Structural composition and main functions

The basic information required for comprehensive evaluation of the device and its parts should be included but not limited to:

1. Detailed description of the overall structure of the device. The system layout drawing, system pictorial drawing and system block diagram should be provided. The system layout drawing should include at least the basic components of the device, clearly identify its key parts and contain sufficient description to help readers understand the drawing. Illustrations should be used to describe the difference of different configurations of the product (if any).

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