Announcement about Publishing Requirements for Medical Device Registration Application Documents and Format of Approval Supporting Documents

by

China Food and Drug Administration (2014 No. 43)

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China Food and Drug Administration

Announcement

2014 No. 43

Announcement about Publishing Requirements for Medical Device Registration Application Documents and Format of Approval Supporting Documents

To regulate medical device registration management and instruct enterprises to complete registration application procedures successfully, China Food and Drug Administration has established requirements for medical device registration application documents and format of approval supporting documents (see Annexes 1-8) based on Regulation on Supervision and Administration of Medical Device (No. 650 order of the State Council) and Regulation on Registration of Medical Device (No. 4 order of China Food and Drug Administration). They are hereby published and will come into effect on October 1, 2014.

It is hereby notified above.

Annexes: 1. Medical Device Registration Certificate of the P.R.C. (format)

2. Medical Device Registration Modification Document of the P.R.C. (format)

3. Medical Device Clinical Trial Approval by China Food and Drug Administration (format)

4. Requirements for Medical Device Registration Application Documents and Description

5. Requirements for Medical Device Renewed Registration Application Documents and Description

6. Requirements for Medical Device Registration Modification Application Documents and Description

7. Requirements for Medical Device Clinical Trial Approval Documents and Description

8. Essential Requirements Checklist of Safety and Effectiveness of Medical Devices

China Food and Drug Administration

September 5, 2014

Annex 1

Medical Device Registration Certificate of the P.R.C.

(format)

Registration certificate number:

Registrant name	
Registrant address	
Production address	
Agent name	(Applicable to imported medical devices)
Agent address	(Applicable to imported medical devices)
Product name	
Model and specification	
Structure and compositions	
Applicable range	
Attachment	Product technical requirements
Other contents	
Remarks	

Approval authority:

Approval date: YY MM DD

Valid until: YY MM DD

(seal of the approval authority)

Annex 2

Medical Device Registration Modification Document of the P.R.C.

(format)

Registration certificate number:

Product name	
Modification	"*** (former registration content or item) "is changed to"*** (new content)".
Remarks	This document is used in conjunction with " "registration certificate.

Approval authority:

Approval date: YY MM DD

(seal of the approval authority)

Annex 3

Medical Device Clinical Trial Approval by China Food and Drug Administration

(format)

Approval number:

Applicant	
Applicant address	
Name of the medical device for trial	
Model and specification of the medical device for trial	
Structure and compositions of the medical device for trial	
Review opinions	
Delivered to	
Copy to	
Remarks	

Approval authority: Approval date: YY MM DD

(seal of the approval authority)

Annex 4

Requirements for Medical Device Registration Application Documents and Description

Level 1 title of the application documents	Level 2 title of the application documents
1. Application form	
2. Supporting documents	
3. Essential Requirements Checklist of Safety and Effectiveness of Medical Devices	
4. General documents	4.1 Overview 4.2 Product description 4.3 Model and specification 4.4 Packaging description 4.5 Applicable range and contraindication 4.6 Reference to predicate products or previous generation of products (if any) 4.7 Other information to be clarified
5. Research documents	5.1 Product performance study 5.2 Biocompatibility evaluation study 5.3 Bio-safety study 5.4 Sterilization and disinfection process study 5.5 Valid period and packaging study 5.6 Animal study 5.7 Software study 5.8 Others
6. Production and manufacturing information	6.1 Description of production process of passive/active products 6.2 Production site
7. Clinical evaluation data	
8. Product risk analysis data	
9. Product technical requirements	
10. Product registration inspection report	10.1 Registration inspection report 10.2 Pre-evaluation opinions

11. User instructions and label sample	11.1 User instructions 11.2 label sample for minimum sales units
12. Compliance statement	

The registration application documents should contain the contents of the submission, including Level 1 and Level 2 titles of the application documents. The content under Each Level 2 title should have separate page numbers.

I. Application form

II. Supporting documents

(1) A domestic applicant should submit the following:

1. A copy of the business license and a copy of the organization code certificate.

2. During a registration application for a domestic medical device according to Special Review Procedures for Innovative Medical Devices, the applicant should submit the inspection notice for special review of innovative medical devices, and production permit and assignment agreement if production of the samples is assigned to other enterprises. The scope of the production permit should cover the type of product under application.

(2) A foreign applicant should submit the following:

1. A marketing certificate for the product in question issued by the medical device authority in the country (region) where the foreign applicant is registered or where the production site is located, and enterprise qualification documents.

2. If the product in question is not managed as a medical device in the country (region) where the foreign applicant is registered or where the production site is located, the applicant needs to provide relevant supporting documents, including marketing permit for the product in question in the country (region) where the foreign applicant is registered or where the production site is located.

3. Letter of authorization, agent commitment, and a copy of business license or organization registration certificate of the agent assigned by the applicant in China.

III. Essential Requirements Checklist of Safety and Effectiveness of Medical Devices

Documents used to describe methods adopted to meet relevant requirements in the products with Essential Requirements Checklist of Safety and Effectiveness of Medical Devices (see Annex 8) and show their compliance. For requirements defined in Essential Requirements Checklist of Safety and Effectiveness of Medical Devices that are not applicable, the reason should be described.

For documents contained in the product registration application documents, their specific location should be indicated. For those not contained in the product registration application documents, the name of such documents and their numbers in the quality management system should be indicated for reference.

IV. Overview documents

(1) Overview

Describe the basis for determining product administration class, classification code, and name.

(2) Product description

1. Passive medical device

Describe product working principle, operation mechanism (if applicable), structural compositions (including auxiliary accessories), main raw materials, and characteristic differences with other similar products. Illustrations should be provided if necessary.

2. Active medical device

Describe product working principle, operation mechanism (if applicable), structural compositions (including auxiliary accessories), main functions and functions of components (critical components and software), and characteristic differences with other similar products. Illustrations should be provided if necessary.

(3) Model and specification

For products with multiple models and specifications, the difference between these models and specifications should be clarified. Comparison tables or pictures or diagrams with captions should be used to describe structural compositions (or configurations), functions, product features, operation modes, and performance indicators of different models and specifications.

(4) Packaging description

Information about product package and package of the accessories sold together with the product. For sterile medical devices, information about initial package suitable for the sterilization method should be described.

(5) Applicable range and contraindication

1. Applicable range: It should be clarified that the treatment and diagnosis functions provided by the product meet the purpose defined in Clause 76 of Regulation on Supervision and Administration of Medical Device, and the applicable treatment stages can be described as well (such as monitoring after treatment, rehabilitation, etc.). The target users and skills/knowledge/training required for operating the product should be clarified. Indicate if the product is disposable or reusable, and indicate which devices are intended to be used in conjunction with it.

2. Intended use environment: Intended use sites of the product such as medical institution, lab, ambulance, or household, and environment conditions that may impact its safety and effectiveness (such as temperature, humidity, power, pressure, and movement).

3. Target user: Information about target user groups (such as adults, children, or newborns), patient selection criteria, parameters to be monitored during use, and other considerations.

4. Contraindication: If applicable, describe the diseases, conditions or groups for which the device should not be used (such as children, old people, pregnant or lactating women, and patients with hepatic or renal function insufficiency).

(6) For referenced predicate products or previous generations of products, relevant information about such predicate products (already on domestic or foreign market) or

previous generations of products (if any) should be provided. Describe the background and purpose for developing the product in question. For predicate products, describe the reason for choosing them as the reference.

Us comparison tables to show identical and different features between the product in question and the reference products (predicate products or previous generations of products) in terms of operation principle, structural compositions, production materials, performance indicators, action mode (such as implant or intervention), and applicable range.

(7) Other information to be clarified. For approved parts or auxiliary accessories, the approval document number and a copy of such document should be provided. Expected combination use with other medical devices or common products should be indicated. Physical and electrical connections between different combinational medical devices in a system should be described.

V. Research documents

Provide applicable research documents for the product in question.

(1) Product performance study

Provide product performance research data and description about study and development of product technical requirements, including functional and safety indicators (such as electrical safety and EMC, radiation safety), basis for determining other quality control related indicators, standards or methods adopted, reason for adopting them and theoretical basis.

(2) Biocompatibility evaluation study

The biocompatibility of the materials used in made products that may contact the patients or users directly or indirectly should be evaluated.

Biocompatibility evaluation study data should include the following:

1. Basis and methods for biocompatibility evaluation.

2. Description of product materials and nature of contact with human body.

3. Reason and justification for implementation or exemption of biological tests.

4. Evaluation on existing data or test result.

(3) Bio-safety study

For products with bio-safety risks that contain allogeneic materials, animal origin materials, or bioactive matters, the bio-safety data of relevant materials and bioactive matters should be provided, including description about the method for sampling tissues, cells, and matters, treatment, storage, testing, and processing flows, the origin (including details of donator screening), verification tests for removal or deactivation methods against viruses, other pathogens, and immunogenic matters, and a short summary of process verification.

(4) Sterilization/disinfection process study

1. Sterilization by the manufacturer: Clarify the sterilization process (method and parameters) and the sterilization assurance level (SAL), and provide a sterilization

confirmation report.

2. Sterilization by the end user: Clarify the recommended sterilization process (method and parameters) and basis for determining such method. For products that can tolerate two or more sterilization cycles, study data about tolerance of the product with the recommended method should be provided.

3. Remaining toxicity: If the sterilization method is likely to cause remaining toxicity, clarify the residue information and corresponding treatment method, and provide relevant study data.

4. Sterilization by the end user: Clarify the recommended sterilization process (method and parameters) and basis for determining such method.

(5) Package valid period and packaging study

1. Determination of valid period: If applicable, provide a product valid period verification report.

2. For a medical device to be re-used for a limited number of times, data verifying the allowed number of uses should be provided.

3. Package and package integrity: Give the basis for keeping package integrity in the claimed valid period and transport and storage conditions.

(6) Pre-clinical animal test

If applicable, describe purpose, results and records of animal tests.

(7) Software study

For software-containing products, a separate medical device software description document should be provided, including basic information, implementation process, and core algorithms. The level of details depends on software security level and complexity. In addition, a statement about software version naming rules should be given to clarify all fields in the version number and their meaning. The full version and issue identification version of the software should be defined.

(8) Other data

Other research data showing product safety and effectiveness.

VI. Production and manufacturing information

(1) Passive medical device

Clarify product manufacturing and treatment processes. Note critical and special processes and indicate the process control points. Clarify use of different processing agents and control of impurities (such as remaining monomer and small molecular residues) during manufacturing.

(2) Active medical device

Clarify the manufacturing process by means of such as flow chart, and indicate the process control points.

Note: For certain active medical devices (such as pacemaker and leads), the production process description in paragraph (1) of VI. Production and manufacturing information

should be considered.

(3) Production site

In case of multiple development and production sites, the actual conditions of each development and production site should be described briefly.

VII, Clinical evaluation data

Submit clinical evaluation data according to relevant rules. For imported medical devices, the clinical evaluation data used during marketing approval of the product in question by the corresponding foreign medical device authority.

VIII, Product risk analysis data

Product risk analysis data are records of product risk management processes and their evaluation results. Traceability of each of the following process should be provided for every identified hazard:

(1) Risk analysis: Including determination of medical device applicable range, safety related characteristics, potential hazards, and risks of each hazardous scenario.

(2) Risk evaluation: Evaluate and determine if risk reduction is needed for each identified hazardous scenario.

(3) Results of implementation and verification of risk control measures. Make reference to testing and evaluation reports if necessary, such as medical electrical safety and biological evaluation.

(4) Acceptability evaluation of any one or more residual risks.

IX, Product technical requirements

Medical device product technical requirements should be developed according to Guidelines for Medical Device Product Technical Requirements. The product technical requirements should be made in duplicate, and accompanied by a statement indicating that the two copies are completely the same.

X, Product registration inspection report

Provide a registration inspection report and pre-evaluation opinions produced by a qualified medical device inspection body

XI, User instructions and label sample of minimum sales units

This information should meet requirements of relevant laws.

XII, Compliance statement

(1) The applicant states that the product in question complies with Regulation on Registration of medical device and relevant laws, classification requirements defined in Medical Device Classification Rules, and current national and industrial standards. A standard compliance list should be provided.

(2) A statement to guarantee authenticity of the submissions (produced by the applicant for domestic products, and by the applicant and agent separately for imported products).