Attachment I

Requirements and Instructions for Filing Data of Class I Medical Devices

I. Filing Data

(A) Filing form for Class I medical devices

(B) Safety risk analysis report

Prepare the report according to the relevant requirements specified in YY 0316 "Application of Risk Management to Medical Devices", and the content of the report mainly include judgment of the intended use of the medical device and safety-related features, determination of hazards, and the assessment of the risk of each hazardous situation; for each determined hazardous situation, evaluate and determine whether needed to reduce the risk; results of implementation and verification of risk control measures, and provide a reference to the inspection and evaluation of reports as necessary; assessment of the acceptability of any one or more of the residual risks, and forming a risk management report.

For IVD products, a risk management report shall be prepared based on the risk analysis, risk evaluation and corresponding risk control over the intended use, possible miss use, safety-related features, determination of known and foreseeable hazard as well as estimate of the risk patients during each link of the product life cycle.

(C) Technical requirements

Technical requirements should be prepared in accordance with the "Guidelines for Preparation of Technical Requirements of Medical Devices".

(D) Product inspection report

The product inspection report shall be self-test report or commission inspection report of the full-item product performance, and products tested should be typical models of the product.

(E) Clinical evaluation data

1. Detail the intended use of the product, including the functionality the product provided, and describe the applicable medical stage (such as post-treatment monitoring, rehabilitation, etc.) of the product, the target users of the product and the skills / knowledge / training required for the operation of the product; devices expected to be used with or to be combined with.

2. Detail the expected use environment of the product, including the intended use location of the product, such as hospital, medical / clinical laboratories, ambulance, family, etc., and the environmental conditions (such as temperature, humidity, power, pressure, moving) that may affect their safety and effectiveness.

3. Detail the population the product applicable to, including information about the target patient population (eg adults, children or newborns), information about patient selection criteria, and the parameters needed to be monitored during the use of the process, and factors to be considered.

4. Detail contraindications of the product, a disease or condition shall be prohibited from the use of the product should be clearly stated if applicable.

5. Description of the comparison with the clinical use of the listed similar products.

6. Description of the adverse events of similar products.

(F) Instruction for Use of the product and label design sample of the smallest sales unit

The IFU of the medical devices shall comply with the requirements of the regulations. A copy of the IFU in its original language and Chinese translation text approved or recognized by oversea governmental authorities should be submitted for imported medical products.

For IVD products, IFU should be prepared in accordance with the relevant requirements of "Guidelines for Preparation of IFU of In Vitro Diagnostic Reagents", with reference to the relevant technical guidelines. For imported vitro diagnostic reagents, a copy of the IFU in its original language and Chinese translation text approved or recognized by oversea governmental authorities should be submitted for imported medical products.

(G) Manufacturing information

An overview of the production process-related conditions shall be provided. For passive medical devices, the production process should be clearly stated, and the key processes and special process shall be noted. For active medical devices, descriptive information about the production process should be provided, it may be in the form of a flowchart, which is an overview of the production process.

For IVD products, the main production processes should summarized, including description of the solid phase carrier, and the color developing system and its determination basis, and the reaction system including the sample collection and handling, sample requirements, sample size, reagent amount, reaction conditions, calibration method (if necessary), and quality control methods.

Description of the actual condition of the development and production of the product shall be provided.

(H) Proof documents

1. Documents the domestic filing party shall provide: a copy of business license and a copy of the organization code certificate.

2. Documents the oversea filing party shall provide:

   (1) Corporate qualification documents of the oversea filing party.

   (2) Proof documents on the marketing of the product issued by the department in charge of medical devices in the country (region) where the registration address or the production address locates of the oversea filing party. For products that are not managed as medical devices in the country (region) where the registration address or the manufacture address locates of the oversea filing party, the filing party is required to provide relevant documents, including a proof document on the legal marketing of the product issued by the department in charge of medical devices in the country (region) where the registration address or the production address locates. If the document is a copy, it shall be notarized by a local notary office.

3. A copy of the power of attorney of the oversea filing party designating agent in China, a copy of the letter of commitment of the agent and copy of business license or registration certificate.

(I) Statement of conformity

1. Statement on compliance of the filing medical devices with requirements;

2. Statement on this product meeting the requirements of catalog of class I medical devices or the sub-catalog of appropriate in vitro diagnostic reagents;

3. Statement on this product complying with current national standards or industry standards, and provide a list of standards-compliant;

4. Statement on the authenticity of the filling data submitted.

II. Change of the filing data

(A) Description of the changes and related proof documents

For description of the changes, a comparison form on the changed content of the filing data should be attached.

For changes related to technical requirements of the product, a comparison form on the changed content of the technical requirements should be attached.

For changes related to the product name (for in vitro diagnostic reagents, referring to the product category name, the same for content below), product description, and intended use, the content after change should be consistent with the catalog of class I medical devices or the sub-catalog of appropriate in vitro diagnostic reagents. Among them, the product name should be the same as that listed in the catalog; the product description or intended use should be the same as or less than that listed in the catalog.

The appropriate proof documents should be detailed, comprehensive and accurate.

(B) Proof documents

1. Documents the domestic filing party shall provide: a copy of business license and a copy of the organization code certificate.

2. Documents the oversea filing party shall provide:

(1) If the change content requires the filing party to obtain a new proof document of the marketing of the product issued by the department in charge of medical devices in the country (region) where the registration address or the manufacture address locates of the oversea filing party, then the new proof document of the marketing of the product should be submitted. If the document is a copy, then it shall be notarized by a local notary office.

(2) A copy of the power of attorney of the oversea filing party designating agent in China, a copy of the letter of commitment of the agent and copy of business license or registration certificate.

(C) Statement of conformity

1. Statement on compliance of the filing medical devices with requirements;

2. Statement on this product meeting the requirements of catalog of class I medical devices or the sub-catalog of appropriate in vitro diagnostic reagents;

3. Statement on this product complying with current national standards or industry standards, and provide a list of standards-compliant;

4. Statement on the authenticity of the filling data submitted.

Attachment: Form requirements for the filing data

Attachment

Form requirements for the filing data

I. The filing data shall be complete and integrate. The filling of the filing form shall be complete.

II. The documents except for proof documents should be provided in Chinese form. If the proof documents are in foreign language, they should be provided in the form of Chinese translation. For applying data based on translation of data in foreign language, the original copy shall be also provided.

III. For the filing data of domestic product, unless otherwise specified, they shall be signed and sealed by the filing party. The "signature and seal" means sealed by the filing party, or signed by the legal representative or responsible person of the filing party and sealed. The seal must be the official seal of the filing party, and it shall not be the registration seal.

IV. For the filing data of imported product, unless otherwise specified, the original data should be the original copy and signed by the filing party, and the Chinese text shall be signed by the agent in China. The "signature and seal" on original data means signed by the legal representative, or responsible person, or signed plus sealed with the organization seal, and a notary copy by local notary organization shall be submitted; Chinese data "signature " means : Agent organization seal, or their legal representative, responsible person plus organization stamped signature .The "signature and seal" on Chinese data refers to sealed with the organization seal, signed by the legal representative plus sealed with the organization seal.

V. The filing data should be provided with a Table of Content of the data submitted, including Level one titles and Level two titles of the whole dossier, and describe each volume and page number in tabular form.

Attachment 2

Filing Certificate for Class I Medical Devices

******(Filing party)：

According to requirements of relevant regulations, the class I medical device: ****** (Product name / Product name) produced by your company has been filed, and the filing number is ******.

**Food and Drug Administration (SFDA)

(China Food and Drug Administration)

(Seal)

Date: Year Month Day

Attachment 3

Filing Data Form for Class I Medical Devices

Filing number:

Name of the filing party	
Organization code of the filing party	(Applicable to domestic medical devices)
Registration address of the filing party	
Manufacture address	
Agent	(Applicable to imported medical devices)
Registration address of the agent	(Applicable to imported medical devices)
Product name	
Model/specification	
Product description	
Intended use	
Notes	
Filing unit and date	**Food and Drug Administration (China Food and Drug Administration) Filing Date: Year Month Day
Change information	On Year Month Day, ** was changed to be **. ……

Filing Data Form for Class I In Vitro Diagnostic Reagents

Filing number:

Name of the filing party	
Organization code of the filing party	(Applicable to domestic medical devices)
Registration address of the filing party	
Manufacture address	
Agent	(Applicable to imported medical devices)
Registration address of the agent	(Applicable to imported medical devices)
Product category name	
Package specification	
Expiration date	
Intended use	
Main components	
Notes	
Filing unit and date	**Food and Drug Administration (China Food and Drug Administration) Filing Date: Year Month Day
Change information	On Year Month Day, ** was changed to be **. ……

Attachment 4

Filing Practice Procedure for Class I Medical Devices

To further regulate the filing of Class I medical devices, this practice procedure is prepared according to "Supervision and Regulation of Medical Devices" and relevant laws and regulations. The filing of Class I medical devices is composed of filing and information release.

I. Filing

(A) Formal examination.

1. The "product name (for in vitro diagnostic reagents, it refers to the product category name, the same for content below)," "product description" and "intended use" in the filing form should be consistent with the catalog of class I medical devices or the sub-catalog of appropriate in vitro diagnostic reagents. Among them, the product name should be the same as that listed in the catalog; the product description or intended use should be the same as or less than that listed in the catalog.

2. Items of the submitted date are complete or not, whether meeting the requirements of filing data.

3. Proof documents are whether in the validity period.

4. The name of the filing party and registration address of the domestic filing party in the filling form are whether consistent with that of the business license.

5. The name of the filing party, registration address, manufacture address and model and specification of the oversea filing party in the filling form are whether consistent with that of the overseas proof documents.

6. The power of attorney of the designated agent by the oversea filing party, the commissioned content and undertakings content in the power of attorney are whether consistent with the filing content.

(B) Matters about the filing belong to the authority range of the department, which should be filed on the spot if the filing information is completed and meet the formal requirements, and provide the filing proof exclusively stamped by the filing party.

(C) It should inform the entire contents needed to been supplemented to the filing party at once time if the filing information is not complete or do not meet the requirements. If cannot been filed, it should inform the filing party and explain the reasons.

(D) If the filing matters do not belong to the authority range of the department, then refuse it, and should inform the filing party and explain the reasons.

(E) The food and drug administration department archives the modification filing information according to the files management procedures of the department.

II、Modify the filing

（A） Form review.

1. If involving the change of product name, product description, and the intended use, it should be consistent with the products catalog of Class I medical devices and classification subdirectories contents of the corresponding diagnostic reagents in vitro after the change. Among them, the product name should be the same as the directory list; the product description and intended use, should be the same as or less than the directory list contents .

2. Whether the submitted information and items are completed and meet the form requirements of filing information.

3. Whether the proof documents is within the validity period.

4. Whether the name of the filing party and registered address of the domestic filing party is consistent with the business license.

5. Whether the name of the filing party, registered address, manufacture address and specifications of the oversea filing party is consistent with oversea proof documents.

6. Whether the power of attorney of designated agent, the commission in the agent pledge letter and pledge contents of the oversea filing party is consistent with filing contents.

（B） The modification filing belongs to the authority range of the department, it will be accepted if the modification information is complete and meet the form requirements.

（C） It should inform the entire contents needed to been supplemented to the filing party at once time if the filing information is not complete or do not meet the requirements. If cannot been filed, it should inform the filing party and explain the reasons.

（D） The Food and Drug Administration department archives the modification filing information according to the files management procedures of the department.

III. Information release

For the filing, the Food and Drug Administration and management department publishes the filing information table of the class I medical devices and diagnostic reagents in vitro on its website. Municipal Food and Drug Administration and management departments should regularly submit the filing information to the provincial Food and Drug Administration and management departments, and provincial Food and Drug Administration and management departments should regularly submit the filing information of the administrative area to the State Food and Drug Administration.

For the modification filing, corresponding Food and Drug Administration and management departments publish the modification column of filing information table of the Class I medical devices and diagnostic reagents in vitro. The submitted information requirements can be referenced in the first paragraph of this article.

Attachment 5

Filing number：_____

Filing Form for Class I Medical Devices (Reference format)

Product name(Product category name): _____

Filing party: _____

Prepared by XX Food and Drug Administration (Prepared by China Food and Drug Administration)

Explanatory notes

1. This table is used for the filing of the import and domestic Class I medical devices and in vitro diagnostic reagents.

2. The column contents required to fill should use Chinese, complete print, clear, must not be blank, should fill out the " / “ if without relevant content. Please enclose the attachment if the filing table form is limited and cannot fill completely.

3. When filing, it should submit the electronic documents (Excel format) containing the filing table contents (including attachments).

4. Only filing party name, registered address and Chinese column of manufacture address should be filled for the domestic medical devices and in vitro diagnostic reagents. The filing party name, registered address and Chinese column of manufacture address can be selected to fill for the imported medical devices and in vitro diagnostic reagents. The Chinese column of the products name (in vitro diagnostic reagents is products name and the same as below) of imported medical devices must been filled.

5. For the system support, the products name, filing party name, registered address and original column of manufacture address of the imported medical device must been filled, original filling contents should be consistent with the registered address of the filing party or specified contents and documents type in the proved certificate document which allows the products to been marketed and issued by Medical Devices competent authorities of the country (region) of manufacture address.

6. The filing party of domestic medical device should fill the organization code.

7. The product name, name of the filing party, registered address and English column of manufacture address for the imported medical device must been filled. If the original is non-English, English content must be consistent with the original.

8. The filled content should be corresponding to the submitted filing information contents.

9. The product categories and classification coding should be based on classification rules and classified catalogue of the medical devices and the products catalogue of Class I medical devices and the sub-categories and related documents of Class I diagnostic reagents in vitro to fill.

10. The registration address column of filing party and agent fill the business license and specified registered address of relevant proved documents of the filing party and agent.

11. The location of the filing party and agent refers to the country (region) or provinces (district and city) of the registered address for the filing party and agent.

12. If other issues required to been specially illustrated, please describe it in the column of “other issues need to been illustrated" of the table.

Note: please read the explanatory notes in detail before completing this form.

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(Product category name)</td><td>Chinese</td><td colspan="4"></td></tr>
<tr><td>Original</td><td colspan="4"></td></tr>
<tr><td>English</td><td colspan="4"></td></tr>
<tr><td>Category number</td><td colspan="5">68</td></tr>
<tr><td>Structural feature</td><td colspan="5">Active □ Passive □ IVD □</td></tr>
<tr><td>Model/specification
(Package specification)</td><td colspan="5"></td></tr>
<tr><td>Product description
(Main components)</td><td colspan="5"></td></tr>
<tr><td>Intended use</td><td colspan="5"></td></tr>
<tr><td>Expiration date(Applicable to diagnostic reagents in vitro)</td><td colspan="5"></td></tr>
<tr><td rowspan="11">Filing party</td><td rowspan="3">Name</td><td>Chinese</td><td colspan="4"></td></tr>
<tr><td>Original</td><td colspan="4"></td></tr>
<tr><td>English</td><td colspan="4"></td></tr>
<tr><td rowspan="3">Registered Address</td><td>Chinese</td><td colspan="4"></td></tr>
<tr><td>Original</td><td colspan="4"></td></tr>
<tr><td>English</td><td colspan="4"></td></tr>
<tr><td>Contact</td><td colspan="2"></td><td>Telephone</td><td></td></tr>
<tr><td>Fax</td><td colspan="2"></td><td>E-mail</td><td></td></tr>
<tr><td>Postcode</td><td colspan="4"></td></tr>
<tr><td>The address of filing party</td><td colspan="4"></td></tr>
<tr><td>Organization code</td><td colspan="4"></td></tr>
<tr><td rowspan="3">Manufacture address</td><td>Chinese</td><td colspan="4"></td></tr>
<tr><td>Original</td><td colspan="4"></td></tr>
<tr><td>English</td><td colspan="4"></td></tr>
<tr><td></td><td>Name</td><td colspan="4"></td></tr>
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<table>
<tr><td rowspan="5">Agent</td><td>Registered address</td><td colspan="3"></td></tr>
<tr><td>Postcode</td><td colspan="3"></td></tr>
<tr><td>Contact</td><td></td><td>Telephone</td><td></td></tr>
<tr><td>Fax</td><td></td><td>E-mail</td><td></td></tr>
<tr><td>The address of the agent</td><td colspan="3"></td></tr>
<tr><td colspan="5">Information should be attached
1. Product risk analysis data □
2. Products Technical Requirements □
3. Product Inspection Report □
4. Clinical evaluation data □
5. Manufacturing information □
6. Product instructions and the smallest sales unit label design comp □
7. Proof documents □
8. Conformity statement □
□</td></tr>
<tr><td colspan="5">Other issues need to been illustrated</td></tr>
<tr><td colspan="5">Filing party/agent(Signature)

Date： Year Month Day</td></tr>
</table>