Procedure for Examination and Approval of Innovative Medical Devices (Trial)

Article 1 To encourage research and innovation of medical devices and promote the growth of innovative medical devices, this Procedure is formulated pursuant to Regulations on Supervision and Management of Medical Devices, the Measures for the Administration of Medical Device Registration and other laws and regulations.

Article 2 The food and drug administration departments examine and approve the medical devices that comply with the following conditions according to this Procedure:

(1) The applicant, through independent technical innovation, acquires the ownership of invention patents of core technology of products in China according to law; or acquires the ownership of or the right to use invention patents in China according to law; or the applicant applies for the invention patents of core technology of products in China which have been promulgated by the competent patent administrative department under the State Council.

(2) The product’s main operating rationales/function mechanisms are domestically initiated, whose performance or safety has been fundamentally improved compared with other products of the same kind, technically taking the lead and boasting conspicuous values of clinical application.

(3) The applicant has finished research on products in early stages and has basically designed the products. The research process is authentic and controlled and the research data are complete and traceable.

Article 3 The food and drug administrations at all levels and related technical institutions, shall arrange the formalities for innovative medical devices with priorities and enhance communications with the applicants according to their respective responsibilities and the requirements provided by this Procedure, in the principle of early intervention, in the charge of the specially-assigned person and scientific examination and approval and under the premises of no lowering of standards or reduction of procedure.

Article 4 The applicant applying for special approval for innovative medical devices shall fill out the Application Form of Special Approval for Innovative Medical Devices (see Appendix 1) and submit the data supporting the applied products complying with Article 2 of this Procedure. The data should include:

(1) The enterprise legal person certificate of the applicant
(2) The intellectual property rights of product and corresponding certificate
(3) The summarization of product research and development process and results
(4) Technical documents for products, at least including:
1. Intended use;
2. Operating rationales/function mechanisms;
3. Major specifications and the basis of determination, the index requirements of major raw materials and key components, major processes and flow charts and the examination methods of key technical indexes.

(5) Credentials for product innovation, at least including:
1. The novelty assessment report issued by the information or patent searching authorities;
2. Academic articles, monographs and overviews that are published in core journals and can sufficiently illustrate the clinical values of the product;
3. Analysis of the application of similar products available at domestic and overseas markets (if any);
4. Innovation of the product and the obvious values in clinical application

(6) Product Safety & Risk Management Report

(7) Product Specification (sample)

(10) Other documents proving that the product is in compliance with Article 2 of this Procedure.

The application data shall be written in Chinese. If the documents are written in foreign languages, they should also have the Chinese version.

The overseas applicant shall authorize his/her agent or agency in China to submit the application.

Article 5 The domestic applicant shall apply to the local provincial food and drug administration for special approval for innovative medical devices. The provincial food and drug administration shall arrange preliminary examination as to whether the applied project meets the requirements of Article 2 of this Procedure and shall issue the review comment of preliminary examination within TEN workdays. The provincial food and drug administration shall notify the applicant of the inconformity to the requirements of Article 2 if the preliminary examination fails and shall submit the application documents and the review comment of the preliminary examination together to the Administrative Acceptance Center (hereinafter referred to as the “Acceptance Center”) of the China Food and Drug Administration (CFDA) if the data comply with the requirements.

The overseas applicant shall apply to CFDA for special approval for innovative medical devices. The Acceptance Center will conduct format examination on the applicant data and will process the approval to those complying with the requirements of Article 4.

Article 6 The Acceptance Center will designate the application serial numbers to the
applications for special approval. The application serial numbers will be sequenced as Device SAP (Special Approval Process) xxxx₁-xxxx₂, of which, xxxx₁ is the year when the application is lodged and xxxx₂ is the serial number of the product when it’s accepted.

**Article 7** CFDA has set up the Examination Office for Innovative Medical Devices (hereinafter referred to as the “Office”) and corresponding expert database to examine the application for special approval for innovative medical devices.

**Article 8** After CFDA accepts the application for special approval for innovative medical devices, the Office will examine the application and issue the review comment within TWENTY workdays. If the Office holds that further examination is needed, an Expert Review Committee composed of experts selected from the expert database will be created to reexamine the application and issue the review comment.

**Article 9** The Office or the Expert Review Committee, after issuing the review comment, shall announce the name of the applicant and that of the products of the applied projects of special approval at the website of the CFDA for no less than TEN workdays. Any objection to the approval shall be decided by final examination after related discussion.

**Article 10** The CFDA shall notify the applicant of the examination result in writing and copy it to the local provincial food and drug administration if the applicant is a domestic enterprise (see Appendix 2 for the format).

**Article 11** The CFDA shall classify management of medical devices in the same course of reviewing the application for special approval for innovative medical devices. For domestic applications, if the products are classified as Class II or Class I medical devices, the CFDA shall notify related information to the local provincial food and drug administration of the applicant. The corresponding provincial or municipal food and drug administration shall conduct follow-up work and conduct examination and approval pursuant to this Procedure.

**Article 12** As for the medical devices approved by CFDA in accordance with this Procedure (hereinafter referred to as the “innovative medical devices”), the local food and drug administration where the applicant is seated shall appoint a special person, as required by the applicant, to provide timely communications and guidance. The administration, after receiving the application from the applicant for Quality Management System examination (checking), shall arrange the application with priorities.

**Article 13** In testing the registration of innovative medical devices, the medical device testing organization shall timely pre-assess the standards of product registration submitted by the manufacturing enterprises and give suggestions for modifications of any problem.

**Article 14** The medical device testing organization shall test the registration of medical devices with priorities after accepting the sample and issue the testing report.
The standards of product registration after the pre-assessment of the medical device testing organization and The Review Comment on Standards of Application for Registration of Medical Devices shall be sealed by the testing organization and issued together with the testing report.

Article 15 The clinical tests of innovative medical devices shall proceed as required by The Regulations of Clinical Test of Medical Devices and other requirements. The food and drug administration shall make supervision and examination according to the process of clinical test.

Article 16 As for the innovative medical devices requiring vital changes of clinical research, such as changes of clinical test plans, regulations of the methods of application, specifications, intended use, the applicable scopes or groups etc, the applicant shall assess the impact of such changes on safety, effectiveness and quality controllability of medical devices. The applicant shall reapply in accordance with this Procedure for the innovative medical devices whose major operating rationales or function mechanisms change.

Article 17 As for the innovative medical devices, before the filing of application for product registration and during technical assessment, the Center for Medical Device Evaluation (hereinafter referred to as CMDE) of CFDA shall appoint special persons to provide immediate communications, guidance and discussion about technical problems related as requested by the applicant.

Article 18 As for the innovative medical devices, the applicant may fill out The Application Form for Communications about Innovative Medical Devices (in Appendix 3) to apply to the CMDE for communications about the following issues:

(1) vital technical problems;
(2) vital safety problems;
(3) clinical test plans;
(4) summarization and assessment of periodical clinical test results;
(5) other vital problems needing communications

Article 19 CMDE shall examine and verify the application for communications and related data promptly and notify the applicant of the results (see Appendix 4). If CMDE approves the communications, it shall explicitly notify the applicant of the issues to be discussed, negotiate with the applicant about the form, time, location and participants of the communication and arrange for communications with the applicant. The communications shall be kept in record and signed by both parties for reference of follow-up research and review of this product.

Article 20 After CFDA files the application for registration of innovative medical devices, it shall mark this project as “innovative medical devices” and circulate the registration application data in a timely manner.
Article 21 CMDE shall conduct technical examination with priorities for the filed registration application of innovative medical devices; after the technical examination is ended, CFDA shall conduct administrative approval with priorities.

Article 22 In the following circumstances, the CFDA may terminate this Procedure and notify the termination to the applicant;

(1) The applicant requests the termination on its own initiative;
(2) The applicant fails to fulfill corresponding obligations within required time limit and according to requirements;
(3) The applicant provides counterfeit and mendacious contents;
(4) The application is not suitable for management according to this Procedure after discussion of the Expert Review Committee.

Article 23 During implementing this Procedure, CFDA shall strengthen communication with related departments of the State Council to know the R & D development of innovative medical devices.

Article 24 Medical devices used for public health emergency shall be dealt with in line with the Procedure of Examination and Approval of Emergency Medical Devices.

Article 25 Any requirement or regulation on management of registration of medical devices not covered by this Procedure shall be implemented pursuant to The Management Methods of Registration of Medical Devices etc.

Article 26 This Procedure shall be effective as of the date of issue.

Appendix 1 Application Form of Special Approval for Innovative Medical Devices

(1) Application Form of Special Approval for Innovative Medical Devices (For domestic applicant)

<table>
<thead>
<tr>
<th>Acceptance No.: Device xxxx1-xxxx2</th>
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<tbody>
<tr>
<td>Name of product</td>
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<tr>
<td>Registered address of the applicant</td>
</tr>
<tr>
<td>Specifications/model</td>
</tr>
<tr>
<td>Performance structure and components</td>
</tr>
<tr>
<td>Major operating rationales/function mechanisms</td>
</tr>
<tr>
<td>Intended use</td>
</tr>
</tbody>
</table>
(2) Application Form of Special Approval for Innovative Medical Devices (For overseas applicant)

<table>
<thead>
<tr>
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<th>Name of applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered address of the applicant</td>
<td>Production address</td>
</tr>
<tr>
<td>Specifications/model</td>
<td></td>
</tr>
<tr>
<td>Performance structure and components</td>
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<tr>
<td>Major operating rationales/function mechanisms</td>
<td></td>
</tr>
<tr>
<td>Intended use</td>
<td></td>
</tr>
</tbody>
</table>

Name of the agency of the applicant in China:_____________________
Contact:_______ Tel.:_________ Fax:_________
Address:_____________ email:_____________ Mobile phone:_________
Application data: (attach a separate page)
Notes:

Signing and/or seal of the applicant:
Signing and/or seal of the agency of the applicant in China:
The person in charge of the agency of the applicant in China (signature):________
Application date:_______________
Appendix 2

Notice on the Examination of the Application for Special Approval for Innovative Medical Devices (NO.: _______)

__________: 

This is to notify that for your application for special approval for innovative medical devices (Acceptance NO.: )

Name of product:
Performance structure and components:
Classification of product management:
Major operating rationales/function mechanisms:

The examination can be concluded that:

□ Agree to be examined and approved according to the Procedure for Examination and Approval of Innovative Medical Devices

□ Disapprove to be examined and approved according to the Procedure for Examination and Approval of Innovative Medical Devices for the reason that_________________

Copy to: ______ Food and Drug Administration (Drug Administration)
(domestic medical devices)

China Food and Drug Administration
(signature and seal)

Date:

Appendix 3

Application Form for Communications about Innovative Medical Devices

<table>
<thead>
<tr>
<th>Name of applicant</th>
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<tbody>
<tr>
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<tr>
<td>Name of product</td>
<td></td>
</tr>
<tr>
<td>NO. of the Notice on</td>
<td>Current stage of</td>
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### the Examination of the Application for Special Approval for Innovative Medical Devices

<table>
<thead>
<tr>
<th>Planned department for communications</th>
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<tbody>
<tr>
<td>Planned methods of communications</td>
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<tr>
<td>Planned topics of communications</td>
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#### Related data of communications

(attach a separate page)

<table>
<thead>
<tr>
<th>Applicants for participation (attach a separate page)</th>
<th>Name</th>
<th>Working unit</th>
<th>Professional title</th>
<th>Specialty</th>
<th>Responsibility</th>
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</tbody>
</table>

#### Notes

Applying unit (seal):_____________ Application date:_____________

Contact:______ Tel.:______ Fax:_______

Address:________ Email:_________ Mobile phone:_________

Note: The applicant shall have complete solutions to or reasonable basis of interpretation of the issues to be discussed when applying for communications.

### Appendix 4

**Reply to Application for Communications about Innovative Medical Devices**

<table>
<thead>
<tr>
<th>Name of applicant</th>
<th></th>
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</thead>
<tbody>
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</tr>
<tr>
<td>Name of product</td>
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<tr>
<td>NO. of Notice on Special Approval for Innovative Medical Devices</td>
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</tr>
<tr>
<td>Application date for communications</td>
<td>Agree or not</td>
</tr>
<tr>
<td>-------------------------------</td>
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</tr>
<tr>
<td>Topics agreed for communications or reasons for disagreement</td>
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<tr>
<td>Meeting time</td>
<td>Venue</td>
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<tr>
<td>Requirements of meeting materials</td>
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<tr>
<td>Planned participating departments (attach a separate page)</td>
<td>Unit and department</td>
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<tr>
<td>Contact information</td>
<td>Contact:__________ Tel.:__________</td>
</tr>
<tr>
<td></td>
<td>Fax:__________ Email:__________</td>
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<tr>
<td>Notes</td>
<td></td>
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