

# Registration of Innovative Medical Devices in China

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国家食品药品监督管理总局医疗器械技术审评中心  
CENTER FOR MEDICAL DEVICE EVALUATION, CFDA

## I

•Policies on Registration of Innovative Medical Devices



## II

•Registration of Innovative Medical Devices

## III

•Registration of Medical Devices with Priority

## ○Regulatory framework of innovative medical devices

### Laws and regulations

#### Regulations for the Supervision and Administration of Medical Devices (Decree of the State Council No. 650)

Article 5 The research and development of medical devices shall follow the principles of safety, effectiveness and cost conservation. The State encourages the research and innovation of medical devices, and will take full advantage of the role of the market mechanism to promote popularization and application of new technologies in medical devices so as to boost the development of the medical device industry.

## ○Regulatory framework of innovative medical devices

### Rules and regulations of the department

#### Administrative Measures for the Registration of Medical Devices (Decree of the CFDA No.4)

Article 8 The state encourages the research and innovation of medical devices, subjects innovative medical devices to special approval, promotes the popularization and application of new technologies for medical devices, and enhances the development of the medical device industry.

Article 9 (part thereof) Where a party applies for registration of a domestic medical device subject to the special approval procedure for innovative medical devices, if it commissions another enterprise to manufacture the sample, it shall select a medical device manufacturing enterprise whose scope of manufacturing covers the product. A party that applies for registration of a domestic medical device not subject to the special approval procedure for innovative medical devices shall not commission another enterprise to manufacture the sample.

Article 79 The emergency approval procedure and special approval procedure of innovative medical devices are formulated separately by the CFDA.



## ○Regulatory framework of innovative medical devices

### Normative documents

- Special Approval Procedure for Innovative Medical Devices (Trial)
- Operation Specifications for the Examination of the Application of Special Approval for Innovative Medical Devices (Trial)
- Operation Specifications for the Communication and Exchange and Technological Review of Innovative Medical Devices (Trial)
- Procedures for Settlement of Disputes Related to the Examination of the Application of Special Approval for Innovative Medical Devices

Effective Date: March 1, 2014

## ○ Registration Requirements of Innovative Medical Devices

- Scope of innovative medical devices

**The following requirements shall be met simultaneously:**

- (1) One or more invention patent(s) for the core technologies of the product has been obtained in China in accordance with the law; or the invention patents or the right to use the patents in China have been obtained through the legal transfer; or the application of the core technology invention patent has been published by the State Council.
  - (2) The main working principle / mechanism of the product is firstly initiated in China, and there is no similar product in the Chinese market; the product's performance or security has a fundamental improvement compared with similar products, also the technology is in the international leading level, and has significant clinical applicable value.
  - (3) The basic product shape has been determined, the research process is real and controlled, and the research data is complete and traceable.
- **Products urgently needed to prevent and control major epidemics are excluded.**

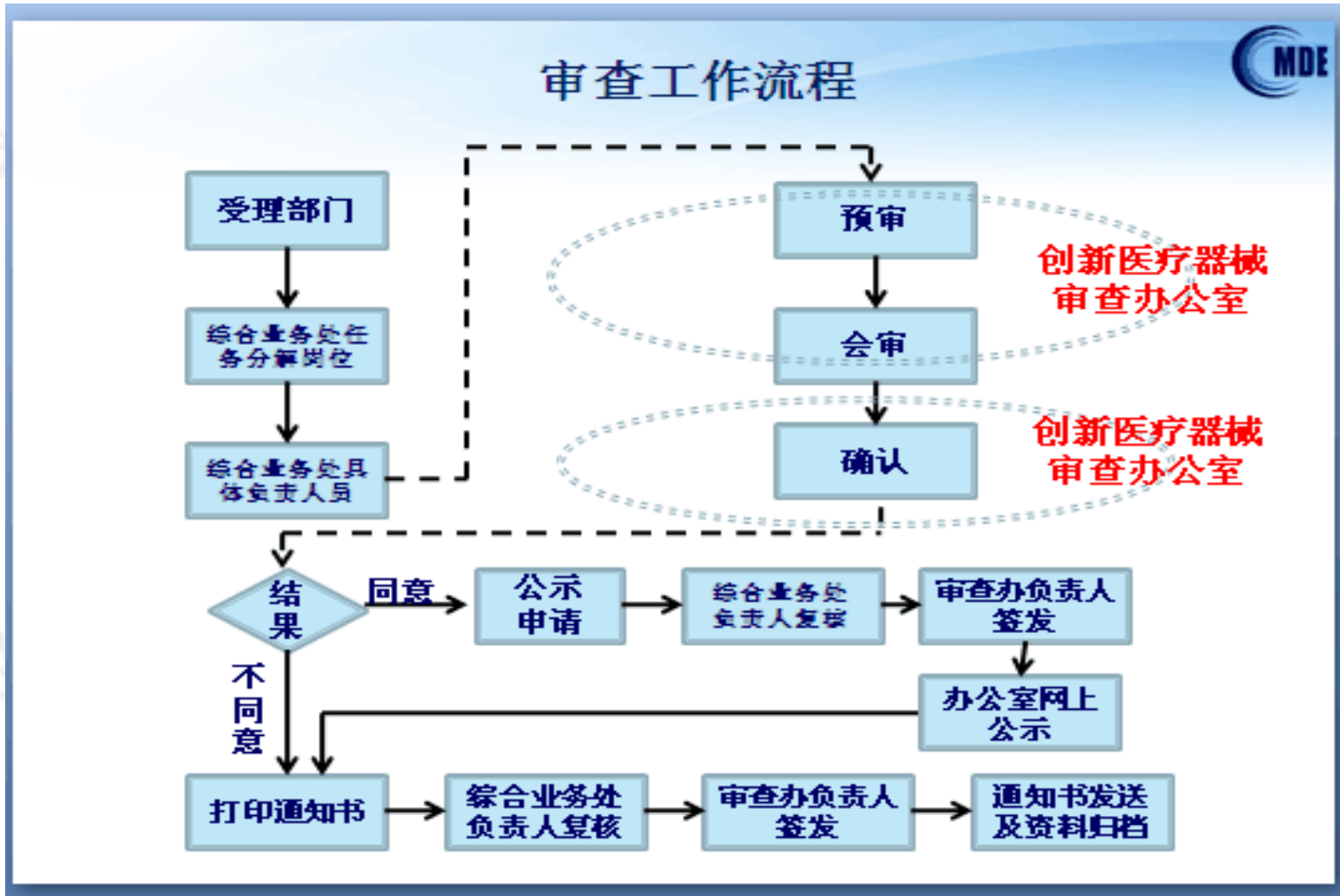
## ○ Registration Requirements of Innovative Medical Devices

- Work principles for the supervision and administration of innovative medical devices

Food and drug supervision and administration departments at all levels and related technical institutions shall, as per their responsibilities and the regulations specified in this Procedure, follow the principles of early intervention, assignation of a special person to take charge, and scientific approval, to prioritize the processing of innovative medical device application and increase the communication and exchange with applicants without lowering the standards and reducing the procedures.

- Organizational structure

CFDA medical device technical review center has set up the Examination Office for Innovative Medical Devices (hereinafter referred to as the Examination Office) to carry out examination on the application of special approval for innovative medical devices.





## Organizational structure----Examination Office for Innovative Medical Devices

The Center has set up the Examination Office for Innovative Medical Devices, which is under the leadership of the Vice Director of the Center, and consists of the Head of the Registration Office under CFDA Division of Medical Device Registration, the Heads of Review Departments of the Center, the Head of Biomedical Engineering Society and the Head of the Secretariat.



## The responsibilities of the Examination Office for Innovative Medical Devices

1. To organize experts to examine the application of special approval for innovative medical devices;
2. To publicize the application of approval to be approved;
3. To review the opinions of experts;
4. To produce and serve the Notice on the Application of Special Approval for Innovative Medical Devices
5. To classify and define innovative medical devices

## Workflow for confirmation of experts' review opinions

- The Examination Office convenes a meeting of members to review the opinions of experts;
- If the opinions are "approved" in the review, then the result will be published as per the procedure. Meanwhile, the management category of innovative medical devices is defined.
- If the opinions are "disapproved" in the review, a notice on review result will be produced along with the disapproval reasons.
- The resolution reached at the members' work meeting is recorded in the minutes of the meeting.

## Registration Requirements of Innovative Medical Devices

### Workflow for confirmation of experts' review opinions

- For applications intended to undergo special examination and approval after the review of the Examination Office for Innovative Medical Devices, the applicant and the product name shall be made public on the website of the CFDA medical device technical review center for no less than 10 business days. If there is any objection to such publicity, the final review decision shall be made after the relevant opinions are studied.

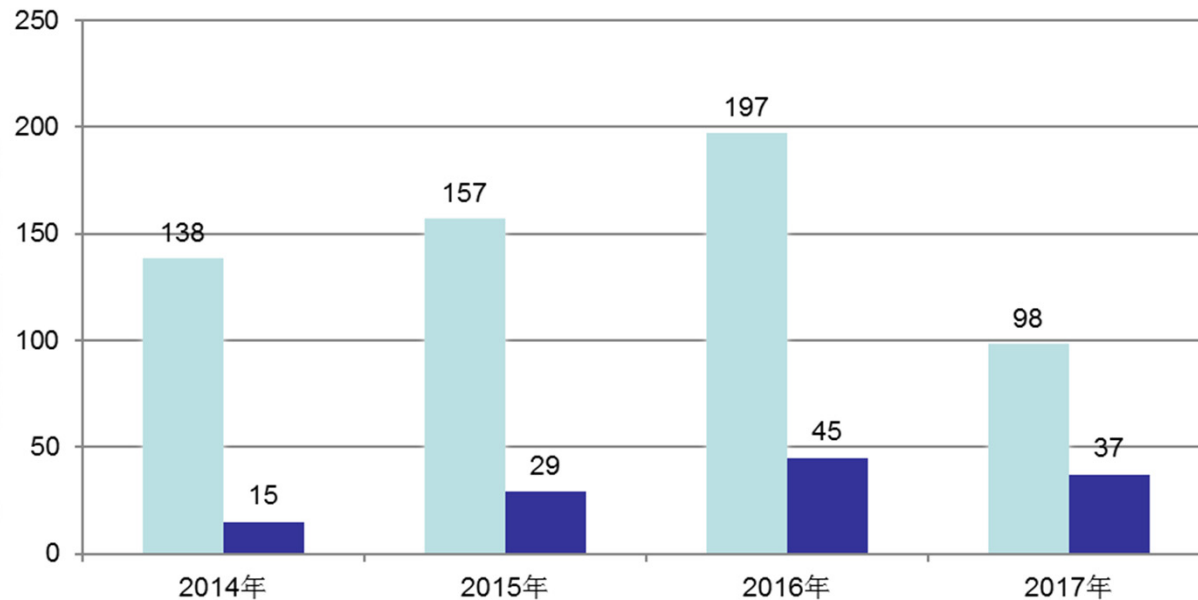


## Workflow for confirmation of experts' review opinions

- After the Examination Office for Innovative Medical Devices makes a decision on the review, the results will be notified in writing to the applicant and the registration authorities. For applications from domestic enterprises, the results shall be also copied to the food and drug supervision and management department at the provincial level where the applicant is located
- For Class III innovative medical devices which are subject to the special approval procedure as agreed, the copy of the notice on examination results shall be sent to relevant offices of the Center at the same time.

As of June 5, 2017, 590 applications for special approval of innovative medical devices have been received, including 28 for imported innovative medical devices. 126 applications were approved, including 10 for imported products.

## Application and approval of innovative products over the past years

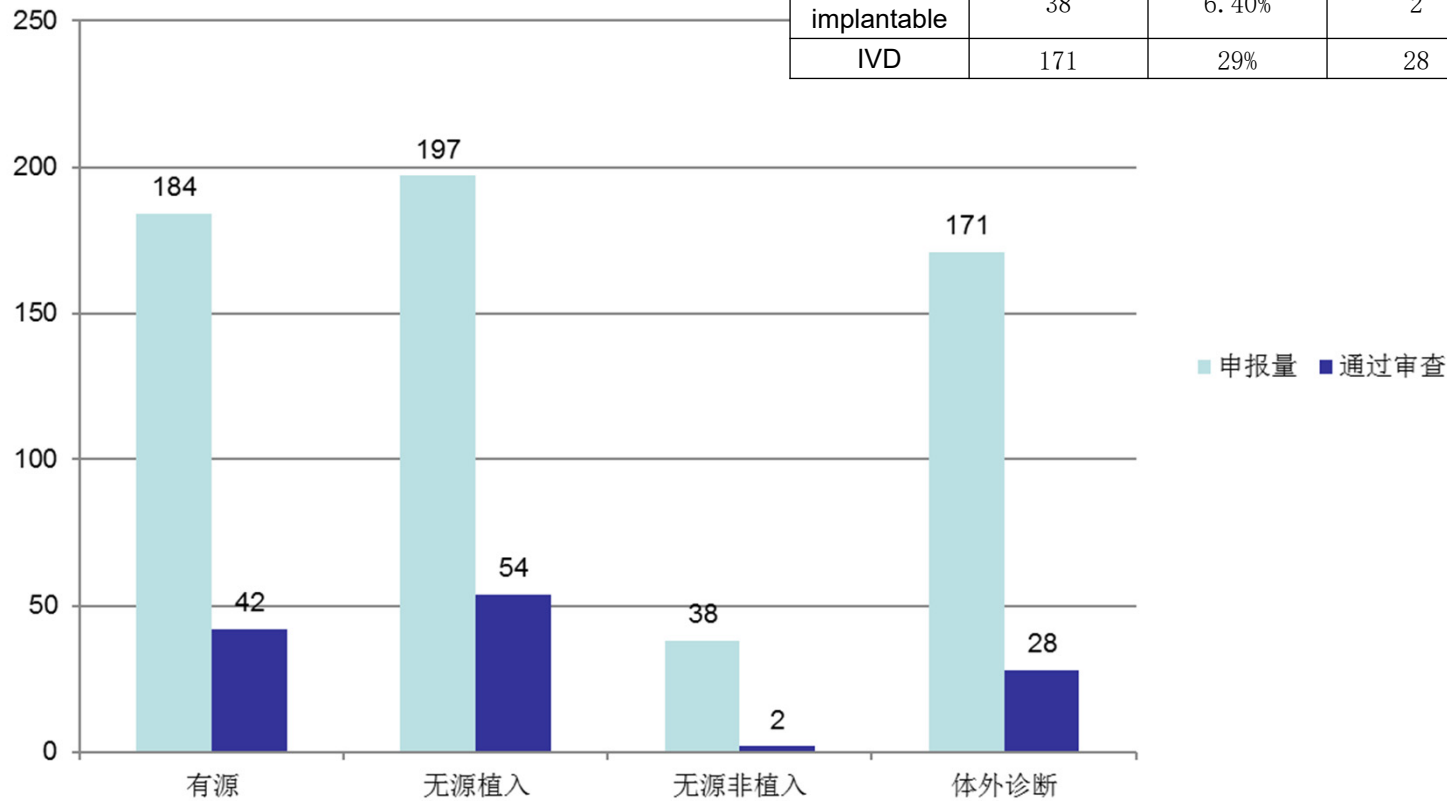


Year	Approval rate
2014	10.90%
2015	18.50%
2016	22.80%
2017	37.70%

■ 申报量 ■ 通过审查

## Statistical breakdown of innovation application and approval

	Applications	Proportion	Approved	Approval rate
Active	184	31.20%	42	22.83%
Passive implantable	197	33.40%	54	27.41%
Passive non-implantable	38	6.40%	2	5.26%
IVD	171	29%	28	16.37%



## Registration Requirements of Innovative Medical Devices

### •Special cases

In any of the following circumstances, the Center can propose to terminate the special approval procedure for innovative medical devices:

- (1) where the applicant has voluntarily requested for termination;
- (2) where the applicant fails to perform the corresponding obligations as required and within the prescribed time;
- (3) where the applicant provides forged or false information;
- (4) where major changes have been made to the composition, major working principle or mechanism, and intended use of the product, and the this Procedure is no longer applicable to the management as determined through the discussion in the expert examination meeting.



- **Communication and exchange**

Before the acceptance of the application for registration and during the technical review process, the Center shall appoint a person, at the request of the applicant, to communicate and provide guidance in time, and discuss relevant technical issues.

- Items to be communicated and exchanged
  - (1) Major technical issues;
  - (2) Significant security issues;
  - (3) Clinical trial programs;
  - (4) Summary and evaluation of the results of periodic clinical trials;
  - (5) Other important issues where there is a need for communication and exchange

## More authoritative experts

- Further expand the pool of experts, and introduce other academic groups

## Work more efficiently

- Work out acceptance requirements, improve the operating procedures, and standardize review requirements

## Make review more transparent

- Improve the existing expert examination methods, and increase interaction and exchange with applicants during the examination process

## Communicate more smoothly

- Develop administrative measures for pre-registration communication and exchange based on the existing regulatory documents

## ○ Regulatory and supervisory framework of medical devices with priority

### Regulatory documents

- **Priority Approval Procedure for Medical Devices: issued by the CFDA on Oct. 26 (No.168 of 2016), effective Jan.1, 2017.**
- **Operation Specifications for the Examination of the Application of Priority Approval for Medical Devices (Trial)**
- **Guidance on the Development of the Application Materials of Priority Approval for Medical Devices (Trial)**



## ○ Review of applications of medical devices with priority

From Jan. 1, 2017 until now, a total of 21 applications for priority approval have been received, and 8 of them have been settled.

3 have been accepted for priority approval procedure, including 2 of national key R&D plans, and 1 urgently needed for clinical application.

13 are under the review of experts.

## ○ Differences between innovation approval and priority approval

Category	Innovative medical devices	Medical devices of priority approval
Requirements	Possess intellectual property right, firstly initiated in China, have significant clinical value, and an essentially finalized design	Urgently needed for clinical use, and strongly supported by the national science and technology departments.
Policies	Enjoy the priority in review and approval, pre-registration communication and exchange, and under the charge of the designated person	Enjoy the priority in review and approval
Application period	Before the application of registration	During the application for registration



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# Prospects of Registration



China

America

Increase the exchange of  
registration experience on  
innovative medical devices



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THANK YOU!