Registration Process of Imported Medical Devices

Tianjin Medical Devise Quality Control & Testing Center

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1 Registration process of overseas medical device products in China

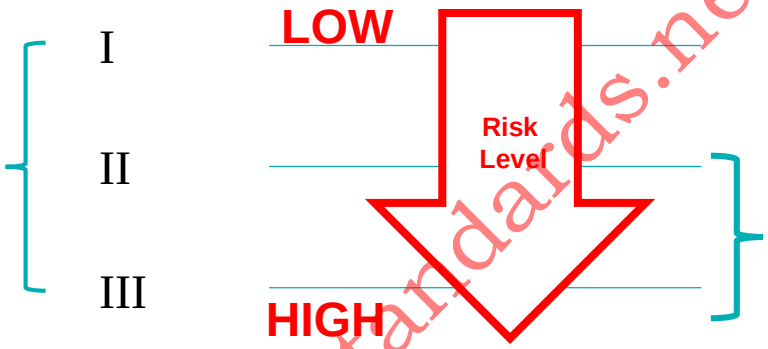
1.1 Basic laws and regulations

Filename	Number
Regulations for the Supervision and Administration of Medical Devices	Order No.680 of the State Council★
Regulations for Registration of Medical Devices	Order No. 4 of China Food and Drug Administration
Regulations for the Specification and Labelling of Medical Devices	Order No. 6 of China Food and Drug Administration
Regulations for Supervision and Administration of Medical Device Production	Order No. 7 of China Food and Drug Administration
Regulations for the Supervision and Administration of Medical Device Management	Order No. 8 of China Food and Drug Administration
Classification Rules of Medical Devices	Order No. 15 of China Food and Drug Administration
Specification for the Quality Control of Clinical Trial of Medical Devices	Order No. 25 of China Food and Drug Administration

1 Registration process of overseas medical device products in China

1.1Basic laws and regulations——Order No.680 of the State Council**--Regulations for the Supervision and Administration of Medical Devices**

Classified administration of medical devices



Record management
(Filing at CFDA)

Registration management
(Apply for registration to CFDA)

Submit the following information when filing or registering:

a. Product risk analysis data;

b. Product technical requirements;

c. test report;

d. Clinical evaluation data;

e. Product description and Label Sample ;

f. Quality management system documents related to product development and production ;

g. Other information required to prove that the product is safe and effective.

1 Registration process of overseas medical device products in China

1.1Basic laws and regulations——Order No.680 of the State Council**--Regulations for the Supervision and Administration of Medical Devices**

An overseas registered applicant for exporting Class II and III medical devices to China shall submit the registration application information and certification documents authorized by the competent department of the original country (region) for listing and selling to CFDA by the representative office established in China or the designated agent in China.

innovative medical devices that are not listed at home or abroad may not submit certification documents authorized from the competent department of the country (region) in which the applicant is registered for the listing and selling of such medical devices.

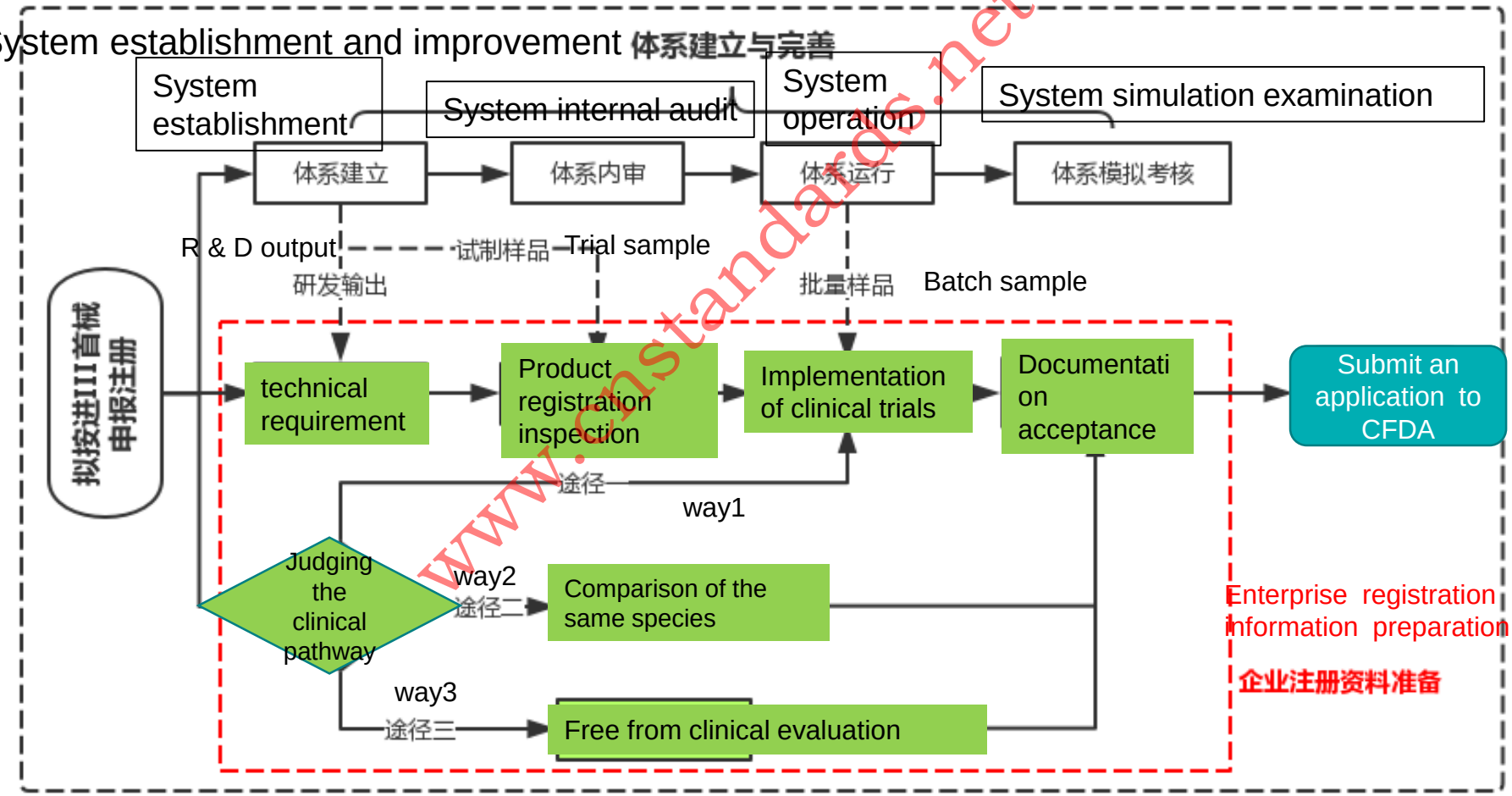
The record holder for filing the class Ⅰ medical device shall submit the product self inspection/test report.

When applying for the registration of Class II and Class III medical devices, registration inspection shall be carried out in accordance with the Technical Requirements for Products.The registered inspection sample shall meet the requirements of the medical device quality management system.

The registration and inspection reports of Class II and Class III medical devices may be self-inspection reports or inspection reports issued by qualified third-party testing institutions.——draft of "Regulations for the Supervision and Administration of Medical Devices" for comments(consultation paper)

1 Registration process of overseas medical device products in China

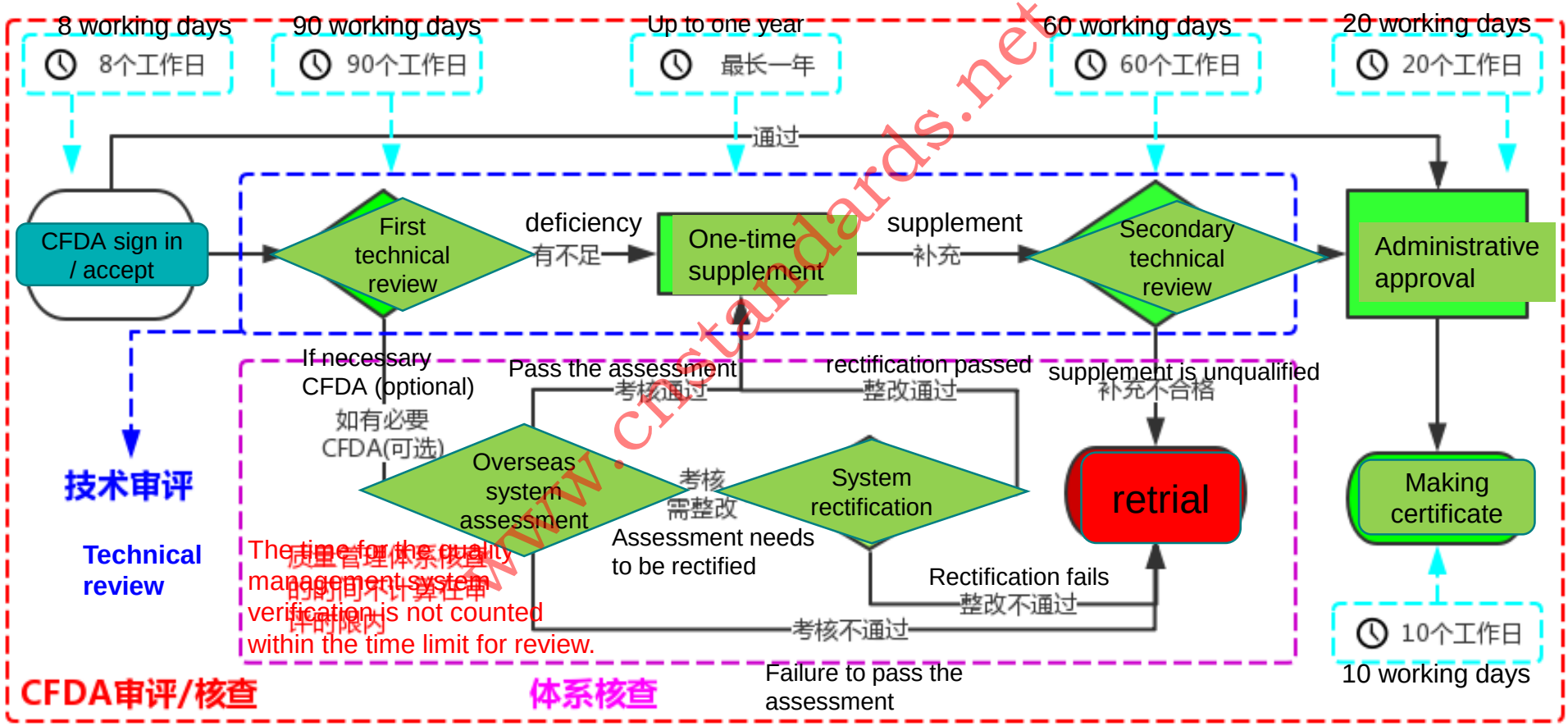
1.2 Registration process——Taking Class III medical device as an example



Information preparation before the first registration is submitted.

1 Registration process of overseas medical device products in China

1.2 Registration process——Taking Class III medical device as an example (

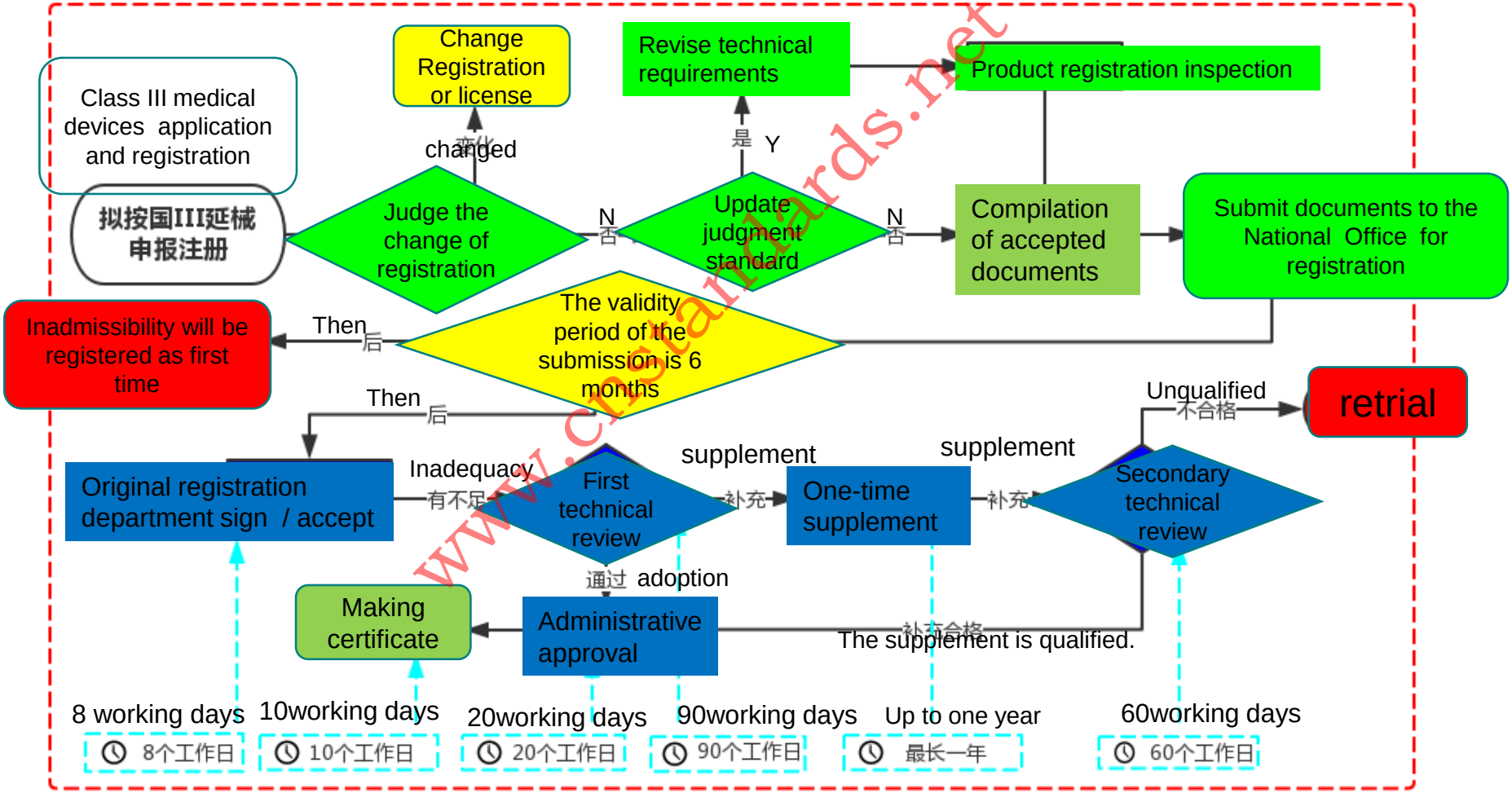


CFDA review / verification

Information review and verification of CFDA after first registration of enterprises

1 Registration process of overseas medical device products in China

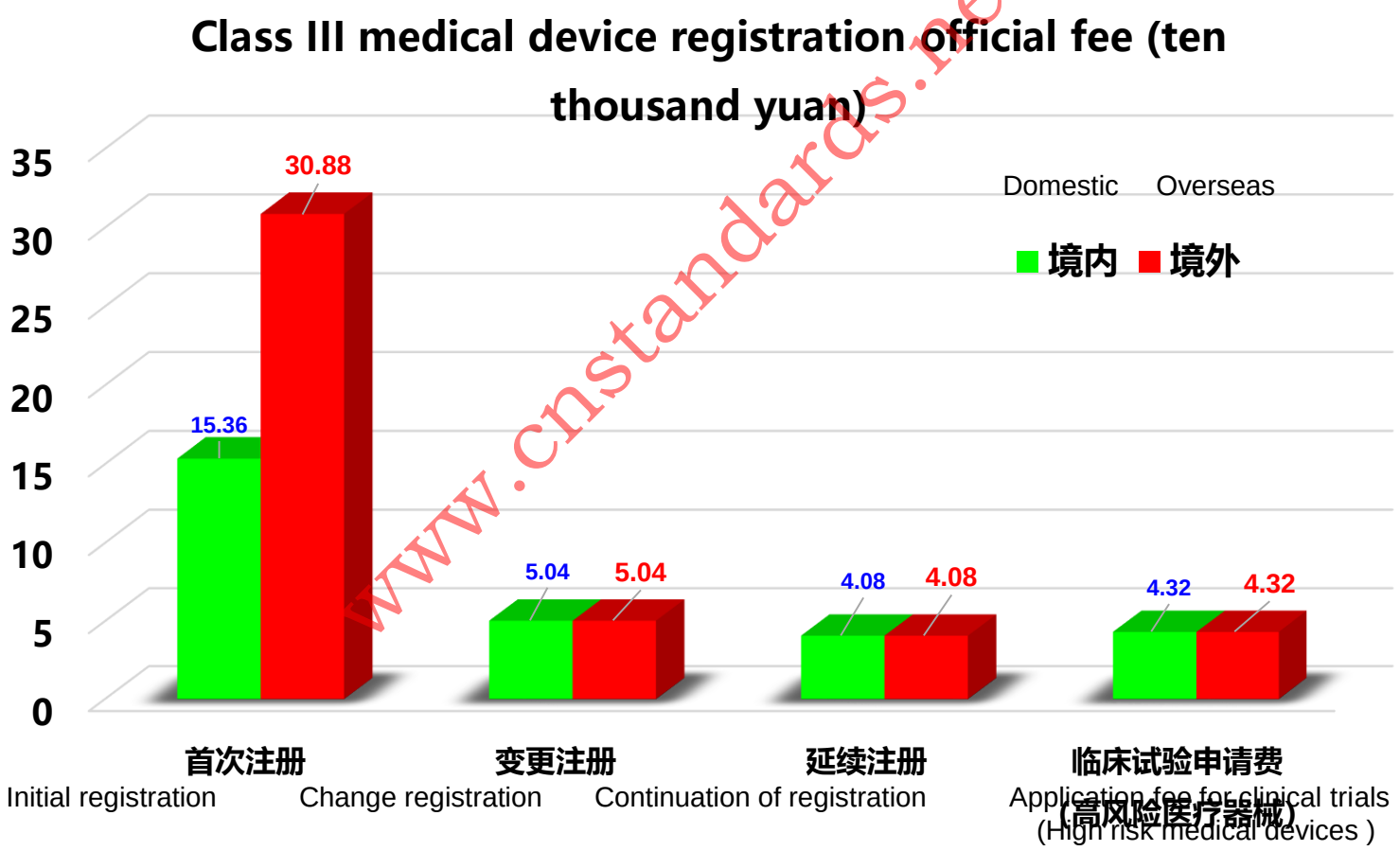
gistration process——Taking Class III medical device as an example(Continuation



Enterprise renewal registration process

1 Registration process of overseas medical device products in China

1.3 Registration official fee——Class III medical device

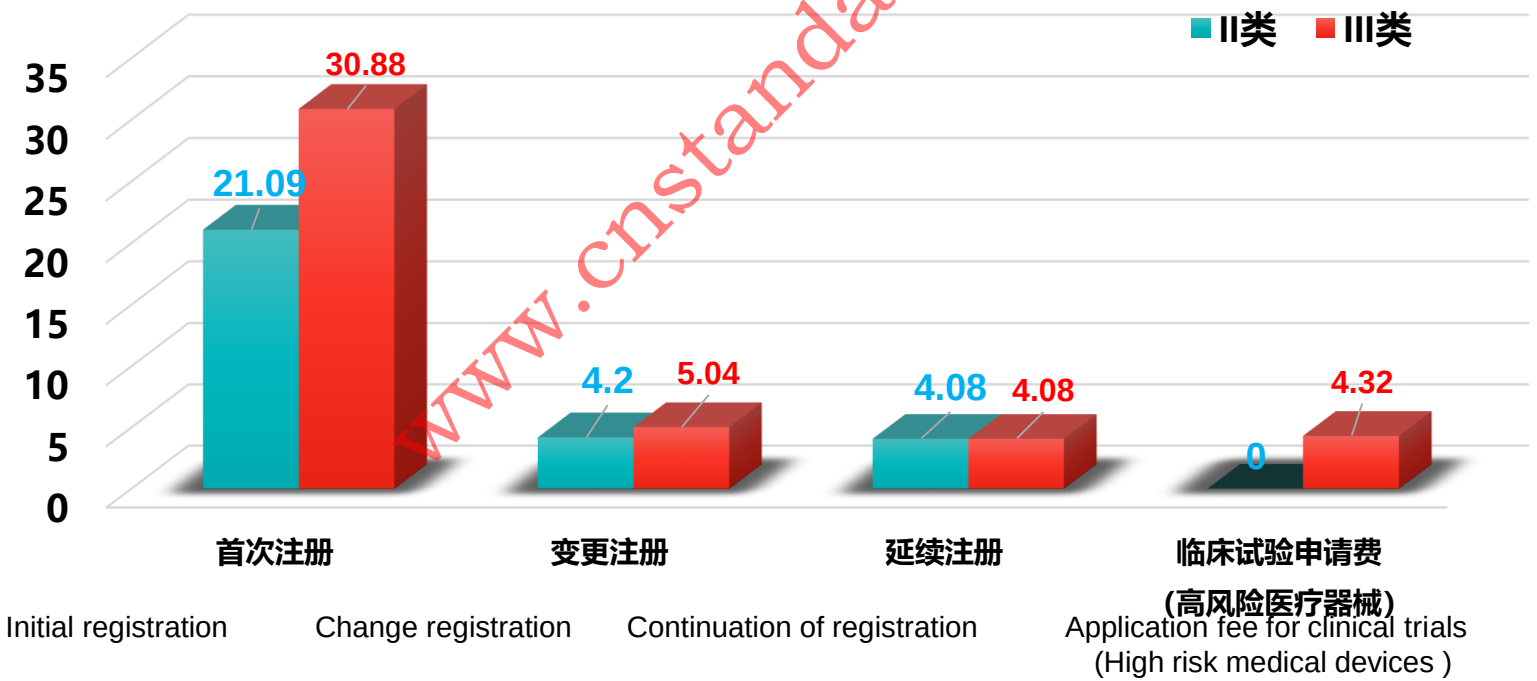


1 Registration process of overseas medical device products in China

1.3 Registration official fee——Comparison of overseas Class II and III instruments devices

Registration of imported Class II and III medical devices

(ten thousand yuan)



1 Registration process of overseas medical device products in China

1.4 Registration schedule——time planning for first registration

- **Proposal stage**

budget, contract, consideration period - estimated 1 month;

- **Data preparation before acceptance**

testing —— the average consumption is 6 months;

Clinical trials —— followed by testing, independent accounting, with an estimated period of one year (excluding clinical products)

- **After acceptance**

CFDA review —— statutory consumption is estimated to be 10 months; (188 working days, 20 working days/month, excluding holidays)

Revision time limit - estimated to be 0~12 months, with an average of 6 months;

System assessment——There is the possibility of CFDA unannounced inspection

- **Total budget——the period for first registration of class III devices without clinical test should be 17~23 months;**

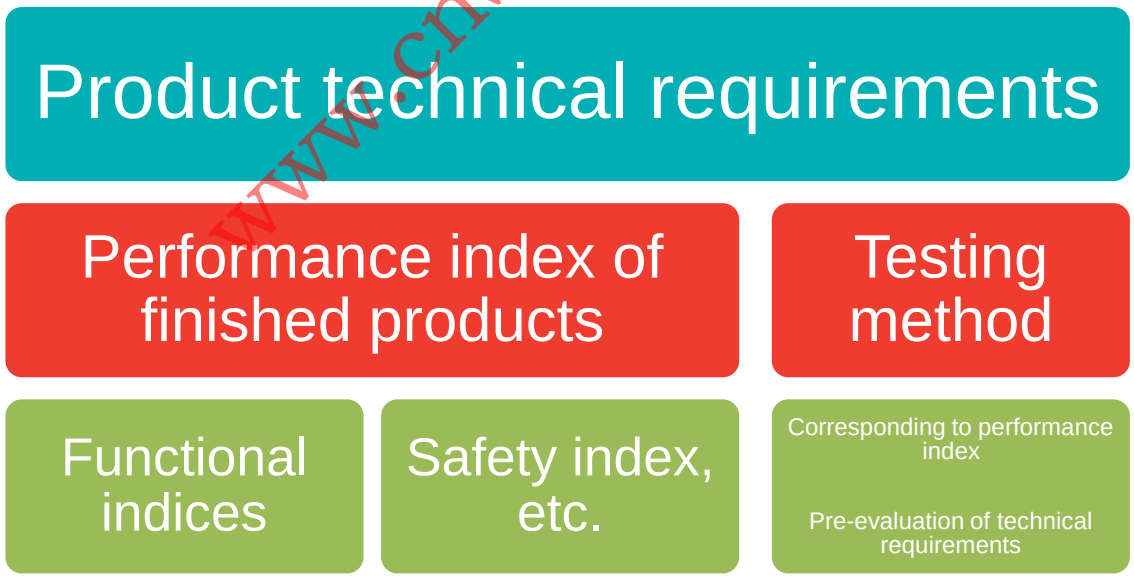
the period for first registration of class III medical devices with clinical test should be at least 35 months;

02 Registration inspection of overseas medical device products

2 Registration inspection of overseas medical device products

- **Draft product technical requirements——Regulations for Registration of Medical Device(**Order No.4 of the State Council**)**

The applicant / filer shall compile the technical requirements for the product. The technical requirements for class Ⅰ medical device shall be s ubmitted to the CFDA. The technical requirements for class Ⅱ and Ⅲ shall be approved by CFDA.



2 Registration inspection of overseas medical device products

- **Inspection ability application**

The medical device inspection institution selected by the enterprise shall have the medical device inspection qualification and conduct inspection within the scope. For medical devices that have not been included in the scope of medical device inspection, the enterprise shall submit an application to the relevant institution for inspection by a competent inspection agency designated by the corresponding registration and approval department. Enterprises should consider it in the test plan of the preliminary planning stage.

- **Inspection unit division**

A multi-model combination unit that can be verified in one test is the most complex combination in the series. In order to avoid missing detection items, it is necessary to divide the units in advance and take it into account in the test plan in the early planning stage.

2 Registration inspection of overseas medical device products

- **Inspection acceptance**

The acceptance of inspection is the initial stage of formal inspection. At this stage, the enterprise shall provide documents and objects to be tested as required by testing institute. The testing institute should be decided at the time of early planning, which is the acceptance stage.

- **Registration test**

The registration test is divided into **the detection acceptance stage**, **the detection rectification stage**, and **the inspection report stage**. The enterprise shall consider the personnel, the measured object and the time in the test plan of the preliminary planning stage.

- **Detection failure survey**

When the test fails, the enterprise should investigate the cause of the test and rebuild the test site so that the R&D engineer can adjust the product until it meets the test requirements

- **Inspection failure rectification**

After the test fails, the company should rectify the equipment to meet the test requirements

03 Standard application in registratio of overseas medical device produ

3 Standard application in registration of overseas medical device products

- **3.1 Basic knowledge of standards**

Framework

- The National Standards for Medical Devices in China shall be formulated by the State Standardization Administration Committee, and shall be examined, approved, numbered and issued in a unified manner. For technical requirements that do not have national standards but need to be unified within the national medical device industry, medical device industry standards can be formulated according to the situation. The industry standards are organized and announced by the State Drug Administration, and reported to the National Standards Administration Committee for the record.
- The medical Device Standardization Technical Committee is responsible for the specific drafting and verification of medical device standards. The Medical Device Standards Management Center established in 2010 organized and coordinated the relevant medical device professional standardization technical committee to carry out the revision of medical device standards, organized research on medical device standard systems, and proposed other work related to standard work policies and planning recommendations.

3 Standard application in registration of overseas medical device products

- **3.1 Basic knowledge of standards**

- **Standardization Technical Committee：** The Standardization Technical Committee is an unincorporated technical organization engaged in standardization work such as standard drafting and technical review in a certain professional field, and is responsible for organizing the drafting of standards in this field. At present, a total of 24 medical device professional standardization technical committees are set up, which are respectively matched with the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO).
- **Status of standards：** According to incomplete statistics, as of September 2018, there are 1580 effective medical device standards in China, including 222 national standards, 1356 industrial standards. According to the nature of standards, there are 497 mandatory standards and 1,081 recommended standards. There are 2 guiding national standards.

3 Standard application in registration of overseas medical device products

- **3.2 Classification of standards**

- We are accustomed to classifying standards into three categories according to the purpose of use: material standards, product standards and test methods standards. Below we take the surgical implant standard as an example.

- Surgical implants use a wide range of materials, including biomedical metal materials, biomedical polymers, biomedical ceramics, biodegradable biomaterials, etc., which are commonly used. The correct use of materials has an important impact on the clinical effectiveness of surgical implants. Therefore, the Surgical Implants Standards Committee has actively transformed most international standards with a conversion rate of over 90%, including ISO 5832, 5833, 5834, 6474, 13356, and 13779 series. However, due to the rapid development of biomaterials in recent years, new materials are emerging, and the development of international standards is relatively slow. The Standards Committee has also actively transformed ASTM (US) standards, EN (EU) standards, BSI (UK) standards, etc. Introduced material standards such as PLLA, PEEK, and Ni-Ti memory alloys to meet the needs of enterprises.

3 Standard application in registration of overseas medical device products

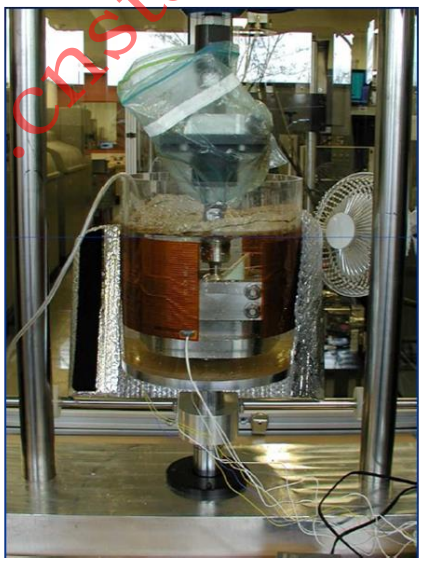
- **3.2 Classification of standards**

- Surgical implant product standards are divided into three levels according to international practice. Level 1 is a general requirement for passive surgical implants; Level 2 is a special requirement for all types of passive surgical implants; Level 3 is for each special requirements for passive surgical implants. The first-level standard include the principled requirements applicable to all passive surgical implants, and some specific requirements are included in the second and third-level standards. The EN ISO 14630, as the first level standard, has been published and has been transformed into the standard YY/T 0640. The second standards ISO 14602 and ISO 21534 have been released and converted into the national standard GB/T 12417. The third-level standard applies to specific implants in certain types of implants. However, due to the slow development of international standards and the high risk of products and the urgency of industry needs，the Standardization Committee has intensified its efforts to revise the standards. At the same time as the international standard of equivalent conversion, a series of American standards were introduced to supplement the blanks of international standards, which made the standard system of surgical implant products more perfect.

3 Standard application in registration of overseas medical device products

- ## 3.3 Application of standards in registration

- Guiding Principles for the Compilation of Technical Requirements for Medical Device Products formulated by the State Food and Drug Administration indicate that the formulation of performance indicators in product technical requirements should refer to relevant national standards/industry standards and combine the design characteristics, intended use and quality control.The level should not be lower than the mandatory national/industrial standards applicable to the product. The establishment of inspection methods should give priority to the use of recognized or enacted standard inspection methods.



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