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for the medical device industry

Medical device registration in China

1. Registration in China

All medical devices to be placed on the market in China need to be registered by the China Food and Drug Administration (CFDA).

2. CFDA registration

CFDA is responsible for the administration and supervision of pharmaceuticals and medical devices.

The Center for Medical Device Evaluation (CMDE) is responsible for the technical evaluation of all types of medical devices imported to China and of domestic Class III medical devices.

Legal basis of the registration of medical devices are the "Regulations for the Supervision and Administration of Medical Devices" implemented on March 7, 2014.

Key points

1. CFDA defines a „medical device" as any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but may be assisted in its function by such means; the use of which is to achieve the following intended objectives: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions; investigation, replacement, or modification of anatomy or a physiological process; life support or sustenance; control of conception; provision of information for the purpose of medicine or diagnosis through investigating samples from the human body.

2. CFDA defines an "in-vitro diagnostic medical device" as any medical device which is a reagent, reagent product kit, calibrator, or control material, whether used alone or in combination with an instrument, apparatus, equipment, or system, intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally during the process of: prediction, prevention, diagnosis, treatment monitoring, or prognosis of disease; health state evaluation.

3. CFDA groups medical devices into three classes according to their risk potential. Class I medical devices are those for which safety and efficacy can be ensured through routine administration; Class II medical devices are those for which further control is required to ensure their safety and efficacy; Class III medical devices are those which require strict control regarding their safety and efficacy.

4. Before medical devices can be placed on the market, the manufacturers must register the products with CFDA. Registration certificates are valid for five years. Six months before expiry of the certificate, certificate holders must apply for their registrations to be extended.

5. The Center for Medical Device Evaluation (CMDE) will decide on registration within 90* working days for Class III medical devices and 60* working days for Class II medical devices.

* The time for decision may be extended.

2.1 Registration documents for imported products

2.1.1 Initial registration for medical devices manufactured outside China

Document list for medical devices (MD)

1. Application form for the registration of imported MD
2. Probative documents
3. Essential requirements list for the safety and effectiveness of medical devices
4. Summary information on the product
5. Research data
6. Manufacturing information
7. Clinical evaluation data
8. Device risk analysis data
9. Product technical requirements
10. Product type test report
11. Design of IFU and label
12. Statement of conformity

Document list for in-vitro diagnostics (IVD)

1. Application form for the registration of imported IVD
2. Probative documents
3. Summary information on the product
4. Research data on critical raw materials
5. Research data on critical production processes and reaction systems
6. Evaluation data on performance analysis
7. Data on positive values or reference intervals
8. Data on stability tests
9. Production and self-test record
10. Clinical evaluation data
11. Device risk analysis data
12. Product technical requirements
13. Product type test report
14. Design of IFU
15. Label draft
16. Statement of conformity

2.1.2 Registration extension

Document list for MD and IVD

1. Application form for registration extension
2. Statement of no changes
3. Copy of the original registration certificate and accompanying documents
4. Copy of all change approvals
5. Product analysis report during valid date
6. Revised product technical requirements (if once changed), two copies
7. Product type test report if mandatory standard has been revised
8. Authorization of the agent
9. Letter of commitment from the agent
10. Copy of the business license and the organization registration certificate from the agent
11. Declaration of conformity
12. Self-declaration from the manufacturer and agent

2.1.3 Registration change

There are two kinds of registration change: licensing item(s) change and registered item(s) change. Changes in the manufacturer's name or address or the agent's name or address fall into the registered item(s) change category. Other changes that do not affect the safety and efficacy including changes of the manufacturing address, the product name, the scope, etc. fall into the licensing item(s) change category. The document lists for licensing item(s) change and registered item(s) change for MD or IVD are very different and depend on the changed item(s).

2.2 Registration test

The situation will be changed in the near future. A self-test report or a third-party report will be used.

2.2.1 Classes II and III

Devices in Classes II and III require type testing carried out in designated test centers in China. Test centers can be selected from the accredited product list. In the case of a series of products with same or similar intended use, technical structure, and specifications, applicants can test a typical representative which embodies the safety and efficacy of the other products.

2.2.2 Test exemption

Imported medical devices cannot be exempted from product type testing. Devices in Classes II or III must be tested in designated test centers, while Class I devices can offer self-test reports.

2.3 Clinical evaluation

2.3.1 Classes II or III

Clinical trials should be carried out in designated clinical trial institutions in China. Only medical devices that are included in the "no clinical trial" catalog can be exempted from clinical trial. IVDs cannot be exempted from clinical trials at present.

2.3.2 Class I

MD and IVD in Class I can be exempted from clinical trials.

2.4 Penalty

Medical devices without registrations are not permitted to enter the Chinese market. Distribution of unregistered products is punishable by law.

3. How can TÜV SÜD help you?

Offering professional expertise and a strong industry network comprising test laboratories, certification bodies, and governmental organizations, TÜV SÜD can help you to achieve efficient CFDA registration. High-quality prereview of your documentation and efficient communication with the relevant authorities are core values of our services.

We can offer the following services:

- Budget and timeline service of Chinese approval
- Technical meeting service of Chinese approval

We look forward to offering our services to you!

Your contact partner at TÜV SÜD Product Service can provide further information.

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