

**GENERAL INTRODUCTION
OF MEDICAL DEVICE
REGISTRATION IN CHINA**

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An increasing number of investors are watching the fast-growing medical device market in China. As the world's most populous country and the fastest-growing economy, China offers vast opportunities for investors in a medical device market that has shown strong growth in recent years. This article provides a general introduction to the registration of medical devices in China.

General Legal Basis

To be sold in China, all medical devices entering the Chinese market are required to obtain pre-market approval from the Chinese State Food and Drug Administration (SFDA). This approval is known as "medical device registration".

China issues registration certificates and licenses in the name of the device manufacturer, not to an agent. Upon registration, a certificate of medical device registration shall not be transferred to any third party, including a new distributor or subsidiary of the manufacturer.

Laws and Regulations

The rules for medical device registration are governed by two main regulations, namely the "Regulations for the Supervision and Administration of Medical Devices" enacted on April 1, 2000, and the "Measures for the Administration of Medical Device Registration" enacted on August 9, 2004. Both regulations describe the legal requirements for obtaining medical device registration in China.

Definition of Medical Device

According to the definition provided in related regulations, a medical device is a tool, apparatus, material or other good, including but not limited to software, that is independently or jointly used on the human body.

Classification of Medical Devices

In order to effectively supervise and manage the medical device market, the SFDA classifies various medical devices into three classes (i.e., Class I, Class II and Class III).

The classes were determined according to device properties, uses and other aspects, essentially based on the risk to the user. Depending on the classification into which the device falls, before the medical device can be placed on the market, different procedures and requirements apply in order to obtain relevant licenses and/or certificates.



Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration;

Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness;

Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness.

For registration, applicants can identify their medical device from the official list provided on the SFDA's website. If the device cannot be identified through the official list, the manufacturer will need to submit an application to the SFDA for class designation of the product, based on the level of safety, structural characteristics and use of the device. In this case, the applicant should construct a detailed introduction of the device, its functions, structural characteristics and classification status in the manufacturer's home country.

Procedures for Medical Device Registration

Overall, the process can be divided into five steps:

1. Appoint an agent (applicant must be a legal Chinese entity);
2. Standards and testing (compliance testing at a designated laboratory in China);
3. Clinical trial (depending on approval and classification, a clinical trial may be required);
4. Application (application and supporting documentation);
5. Evaluation (the Centre for Medical Device Evaluation [CDME] conducts a technical evaluation of the information provided and issues the registration)

Role of an Agent

According to the medical device registration provisions, applications for medical device registration can only be carried out by a legal Chinese entity. Foreign manufacturers of medical devices without a legal representative in China are thus required to apply for product registration through an agent. When using the services of an agent, the manufacturer is required to issue a letter of authorization stipulating the relationship between the agent and the manufacturer.



Designated agents play an important role in the registration of a medical device. In addition to handling the application process and coordinating communication between the administrative authorities and foreign manufacturers, an agent shall also be responsible for the collection of adverse information regarding medical devices and report this to the proper authorities, as well as assist in recalls of the devices in question. Thus, careful consideration should be given when selecting agents. An important selection criteria can be the agent's experience in dealing with regulatory affairs, plus experience in compilation and modification of the registered product standard, etc.

Right of a Medical Device Distributor

Generally, a medical device distributor must obtain specific trading licenses in addition to normal business licenses. Upon obtaining the required trading licenses, medical device distributors have the right to purchase and sell registered medical devices. Medical device distributors have no rights within the medical device registration system, as medical device registration certificates are issued to medical device manufacturers only.

The relationship between the Medical Device Manufacturer's IP rights and registration

Medical device registration is a must for selling specific medical devices in China. Medical device registration is not, however, a precondition regarding intellectual property (such as patent) registration.

Reference:

Regulations for the Supervision and Administration of Medical

Devices Measures for the Administration of Medical Device Registration

Regulations for Further Regulate the Administration of Medical Device Registration

The Official Website of the Chinese State Food and Drug Administration (SFDA) - www.sda.gov.cn



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