

NEWSLETTER

知产快报

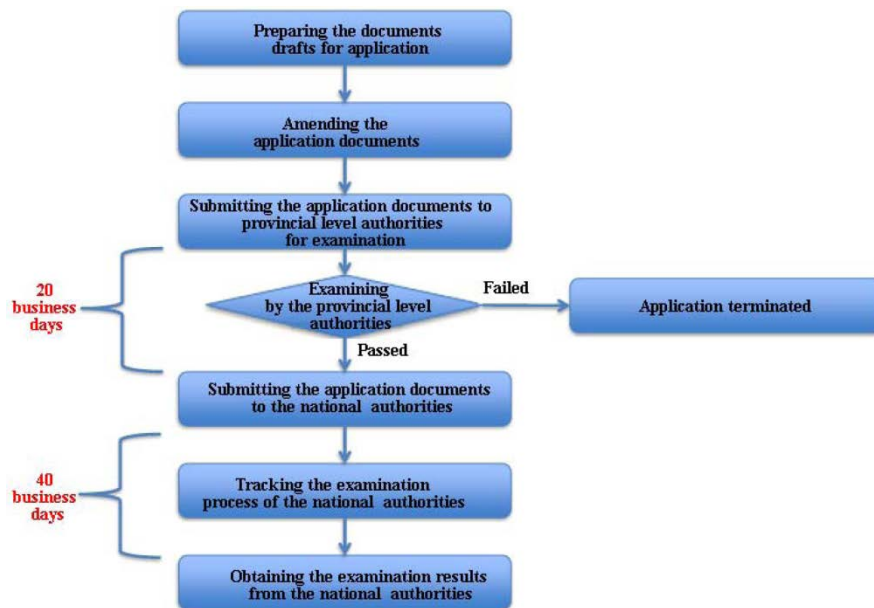
- This article briefly reviews the overall situation since the implementation of the “Special Examination and Approval Procedures for Innovative Medical Devices” and highlights the requirements on intellectual property for the medical device to be declared. We hope it is helpful for the relevant readers.



Green Channel for Innovative Medical Devices Approval in China Requirements on Intellectual Property

In order to encourage the research and innovation of medical devices and facilitate the promotion and application of new medical device technologies, the China Food and Drug Administration (hereinafter referred to as “CFDA,” so-call “NMPA” National Medical Products Administration since November 2018) issued “Special Examination and Approval Procedures for Innovative Medical Devices (Trial)” according to laws and regulations such as “Regulations on the Supervision and Management of Medical Devices” and “Measures for the Registration and Management of Medical Devices” to accelerate the examination and approval of innovative medical devices (green channel). Taking domestic products as an example, the provincial level authorities should perform an initial examination within twenty (20) business days, then the national authorities should provide examination opinions within forty (40) business days. If it is successful, it only takes sixty (60) business days to enter the publicity period. The minimum publicity period is 10 business days. In general, from the time of filing to registration, it is possible to complete the process in about fifteen (15) weeks. Compared with the past, the time required for the examination and approval has been greatly reduced, and the products can be approved for marketing faster.

In short, according to this procedure, those medical devices, which have Chinese invention patents or patent applications, whose working principles/function principles are first created in China, whose technology are at a leading international level and whose products are basically approved, belong to innovative medical devices and can apply for the special examination and approval procedures. The characteristics of this special procedure can be summarized as: early intervention, having dedicated persons in charge, conducting scientific examination and approval and being handled on a priority basis. The specific approval process is shown below:



The special examination and approval procedure were taken effect on March 1, 2014. At the beginning of the implementation, many applications failed to pass the examination due to the low quality of the application materials. To this end, on December 14, 2016, CFDA issued the “Guidelines for the Preparation of Application Materials for Special Examination and Approval of Innovative Medical Devices” (hereinafter

referred to as “Guidelines”) to improve the quality of application materials.

Since the implementation of the special examination and approval procedure to the end of August 2018, CFDA has accepted a total of 967 applications for innovation. Among them, 185 were approved, 64 were registered, and 40 were approved to marketing. These medical devices are mainly active implant, passive implant,

passive non-implant, and in vitro diagnostic medical devices. The overall pass rate is about 30%. The main reason for this lower pass rate is that the declared innovative medical device cannot meet the requirements of Article 2 of the procedure:

(1) Through its technological innovation activities, an applicant owns **patent rights** in China in accordance with law for the core technology of its product, or has acquired the patent rights or related use rights in China through a transfer in accordance with law; or the patent application for such core technology has been published by the patent administration authorities of the State Council.

(2) **The primary working principles/mechanisms of the product are first created in China.** Compared with similar products, the performance or safety of the product has been fundamentally improved. Technologically, it is at a leading international level and has a significant clinical application value.

(3) The applicant has completed the preliminary research on the product and has a **basically approved product.** The research process is truthful and controlled. The research data is complete and traceable.

In particular, the application materials cannot meet the requirements as prescribed under Article 4 of the procedure, especially the requirements concerning the intellectual property rights of the products and the supporting documents, that is, the materials related to the core technology invention patents or invention patent applications do not meet the requirements. For example, the patent documents are not correct or incomplete, the patentee does not conform to the declared project, the patent content does not conform to the declared project, the patent content is not the core technology, the new product search report is unqualified or overdue. This is also the main content of this article.

According to the "Guidelines", the application materials related to intellectual property rights of the application for special examination and approval for innovative medical devices include the information and the proof documents of the intellectual property rights of the products:

1. Information of the intellectual property of the product core technology

If there are multiple invention patents, information such as the title of the invention patent, the patentee and the patent legal status should be displayed in a list.

2. Proof documents of relevant intellectual property rights

(1) If the applicant has obtained the Chinese invention patent right, it shall provide copies of the patent authorization certificate, the claims and the specification signed by the applicant, as well as a copy of the patent register issued by the patent administration authorities.

(2) If the applicant has acquired the right to use the patent rights in China through a transfer in accordance with law, in addition to copies of the patent authorization certificate, the claims and the specification signed by the applicant, the original of the "Certificate of Patent Implementation License Contract", as issued by the patent administration authorities, should also be provided.

(3) If the invention patent application has been published by the patent administration authorities and has not been authorized, copies of documents proving the publish of the invention patent (such as the notice of publication of the invention patent application, the notice of the publication and entering substantive examination stage of the invention patent application and the notice of entering substantive examination stage of the invention patent application), claims and specifications of the published version should be provided. In the examination process of the invention patent application, if the claims and the specifications have been amended under the request of the patent examination department, the amended documents shall be submitted; if the patentee changes, the proof documents, such as a copy of the notice of a qualified registration of a change, issued by the patent administration authorities, shall be submitted.

In summary, the key points on the requirements for intellectual property in applying for the special examination and approval procedures for innovative medical devices are that: the applicant must own the Chinese invention patent or the published invention patent application on its own or through a transfer, and the invention patent or invention patent application should cover the core technology of the innovative medical device to be declared.

As a proof document for an invention patent

or an invention patent application, it may be an invention patent certificate, a notice of publication of an invention patent application, a notice of entry into the substantive examination stage of an invention patent application, a notice of the publication and entry into the substantive examination stage of an invention patent application or a notice of granting an invention patent right. On the other hand, it cannot be a notice of acceptance of a patent application, a notice of preliminary examination of an invention patent application, a notice of entry into the China national phase of an international application, a notice of acceptance of an international application for entry into the China national phase (not satisfied with the requirement for being disclosed in China) or a foreign patent/patent application or a PCT application at the international stage (not protected by Chinese law).

In addition, if the product innovation proof documents include a new product report, which should be a new technology research report issued by an information search agency located in China or a patent search report issued by a

patent search agency located in China. The report is valid for one year and the contents of the report should demonstrate the novelty, the novelty level and reasons for having novelty.

In particular, if the applicant for the special examination and approval procedures for innovative medical devices is an applicant outside of China, he or she shall authorize a corporate person in China as its agent or its offices/branches in China to file an application and shall submit the following documents: a power of attorney, a commitment letter from such an agent or applicant's office/branch; and the business license of such an agent or proof of registration of the office/branch of the applicant in China.

This article briefly reviews the overall situation since the implementation of the "Special Examination and Approval Procedures for Innovative Medical Devices" and highlights the requirements on intellectual property for the medical device to be declared. We hope it is helpful for the relevant readers.

The newsletter is not intended to constitute legal advice. Special legal advice should be taken before acting on any of the topics addressed here.

For further information, please contact the attorney listed below. General e-mail messages may be sent using LTBJ@lungtin.com which also can be found at www.lungtin.com

YU, Baoqing, Partner, Senior Patent Attorney, Head of Domestic Patent Dept.: LTBJ@lungtin.com



YU, Baoqing

(Partner, Senior Patent Attorney, Head of Domestic Patent Dept.)

Mr. Yu is a partner and senior patent attorney at Lung Tin, where he focuses on patent matters, primarily on patent application preparation and prosecution in the fields of electrochemistry, organic chemistry, chemical engineering, material chemistry, and food, and also on providing patent opinions and strategic patent counseling, as well as on patent reexamination, invalidation and litigation. Mr. Yu joined Lung Tin in 2012.