

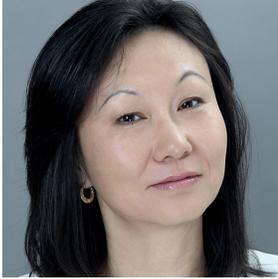
## China's Fast Track for Innovative Medical Device Approvals



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### China's Fast Track for Innovative Medical Device Approvals

*Grace Fu Palma, founder and CEO of Boston-based China Med Device, a firm specializing in commercialization and funding for medtech companies entering China, explains how medtech companies can use a new guideline from the China FDA to help secure fast track approvals for innovative medical devices.*

CFDA issued a new guideline for document preparation of innovative medical device special approval process on Dec. 15, 2016. The initial general decree that governs the general requirements of innovation approval was first issued on Feb. 7, 2014. Since then, a series of documents have spelled out the reviewing and feedback process. CFDA gained more experience in the past 2 years after more than 400 products have been submitted.

This new guideline provides more details to regulate the preparation and writing of documents for the special approval of innovative medical device. There are some important parts of the new guideline for foreign medtech companies who want to gain faster access to China market:

1. Foreign (such as U.S.) medtech companies can also apply for this fast track special approval for innovative medical devices if the foreign companies meet the following requirements (For details, please refer to the Feb 7, 2014 decree).
  - a) **Patent.** The product should have a patent in China. You do not need to wait for the final patent approval to claim your qualification. If you have received the public notice for verification from the China patent office, you can be qualified. Furthermore, the patent does not need to be originated in China. If an entity in China is licensed with the usage or ownership rights of the patent, you can qualify. Therefore, when you apply for new patents and value China medtech market, make sure that you have China PTO coverage.

- b) **Innovation and clinical significance.** The guideline spelled out what types of documents are needed to demonstrate that your medical device will meet this requirement. The product must have significant clinical application value and improvement over the current products in the categories claimed both in China and globally.
  - c) **Prototype product:** The applicant should have completed the preliminary study of the product and have a prototyped product.
2. Once you get the “innovative medical device” designation, you can be put on the fast track with a designated CFDA reviewer and priority status for fast track approval.
  3. The documents required to submit include: 1) Application form; 2) Business Legal Agent certificate; 3) Product intellectual property rights certificate; 4) Overview of product development process and results; 5) Product technical documents; 6) Documentary evidence of product innovation; 7) Product safety risk management report; 8) Instructions for use; 9) Other documents relate to product intellectual property; 10) Agent related information; and 11) Declaration of Authenticity.
  4. Applicant should also submit electronic documents.

The guide provides the details of the required submission documents and their formats.

In summary, U.S. or other foreign companies as well as Chinese medtech companies are eligible to use these guidelines to see if they are qualified and to prepare the necessary documents to gain a fast track to CFDA approval.