SPECIAL APPROVAL PROCEDURES FOR INNOVATIVE MEDICAL DEVICES IN CHINA
What is the Innovative device pathway?

- Based on CFDA Order [2014] No. 13
- In February 2014, the China Food and Drug Administration released Trial Procedures for the Special Examination of Innovative Medical Devices (Special Procedures).
- Under these special procedures, if a medical device meets certain criteria it will be eligible for “priority” evaluation and approval procedures.
- Through this channel, a fast-tracked regulatory approval process is available for medical devices/IVD’s.
- Applicants for these procedures may be domestic or foreign companies.
- Also known as the ‘Green Channel’.
Requirements for eligibility

- **Chinese patent**
  - Applicant must hold a Chinese (invention) patent for an innovative technology or is licensed to use such a patent in China. Alternatively, the applicant should have a patent application under review with preliminary approval publicized by the Chinese National Council.

- **Innovative product**
  - The product must be the first of its kind in China and technically advanced in the global market; it should fundamentally improve product functionality and/or safety when compared to predicate devices and has significant clinical value.
  - The application scope of the core technology in patent document shall be consistent with the application scope of the product.

- **Design progress and records**
  - Applicant should have a prototype developed under a controlled process with a fully traceable design dossier.
The ‘Green Channel’ process for imported medical devices

**Document Preparation**
- Qualification certificate of Applicant – Imported device shall assign an agency or entity in China to be the submission deputy.
- Statement of the ownership of the IP rights and relevant certificates
- Research and Design Overview.
- Technical Documents.
- Certifications for Product Innovation.
- Risk management report
- IFU (sample).
- Other supporting documents.

**Technical Reviewing**
- Acceptance (5 working days) – Pre-Review – Panel Meeting – Result Validation.
- Panel meeting will not be open to public.
- Panel experts will be selected by CMDE Innovative Medical Device Reviewing Office.

**Result**
- The Review result shall be published on the CMDE website for at least 10 working days.
- If there are no comments from the public, the review result will be released to the applicant.

<table>
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<tr>
<th>Applicant</th>
<th>CMDE Innovative Medical Device Review Office</th>
<th>CMDE</th>
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<tr>
<td>3-6 Months</td>
<td>5 + 40 working days</td>
<td>10 working days</td>
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Required Documents for ‘Green Channel’ process

- **Patents**
  - Must be an innovative patent related to product core technology
  - Patent must be registered in and published by China Patent Office
  - If the Patent owner is different from the registration applicant, the legal transfer document of the patent right or patent usage right shall be submitted.
  - The application scope of the core technology in patent document shall be consistent with the application scope of the product.

- **Technical Documents**
  - Product Description
    - Manufacturing flow-chart
    - Critical Quality control points
    - Software description if any
  - Technical Specifications
    - Performance specifications
    - Test Methods
    - China GB/YY standards
  - Research Data
    - Product verification & validation report
    - Animal study report
    - Sterilization and disinfection report
    - Clinical Evaluation Report

- **Research and Design Overview**
  - About Project
    - Project Summary
    - Product Working Principles
  - R&D Overview
    - Product Technical Specifications
    - Designs of the manufacturing process, animal study and clinical studies
  - Results Summary
    - Results summary of product stability, animal and clinical studies

- **Certifications of Product Innovation**
  - Novelty Search Report – Issued within 1 year
  - Academic Publications – focused on clinical value, translated to Chinese.
  - Product Comparison – with those approved in China and globally.
  - Outstanding Clinical Value Report – to substantiate the claim of innovation.
The ‘Green Channel’ has been in effect since 2014. Several devices have been granted “priority” status:

- **BioNTech Diagnostics GmbH**: Human Breast Cancer Molecular Typing Quantitative Detection Kit (PCR – Fluorescent Probe Method) (July 29, 2016)
- **Abbott Vascular**: Absorptive bio-vascular stent system (March 16, 2015)
- **Medtronic**: Micra (October 16, 2015)
- **Boston Scientific Corporation**: Transcatheter Aortic Valve (July 29, 2016)
Advantages of the fast-track approval process

- CFDA will appoint one contact person for pre-assessment consultation and subsequent application review, this person will liaise with the applicant to provide technical guidance.
- Testing center provides preliminary technical feedback during the in-China type testing process.
- Prioritized CTA, technical evaluation and quality system inspection. (6 – 9 months saved).
- Applicant may consult CFDA technical review center on the in-China clinical trial plan and any staged outcomes.
- The registration application is directly assessment by a special team of experts appointed by the Innovative Medical Device Review Office.
- Official device classification category can be decided in parallel with the registration application assessment (no separate classification application required even if no existing classification code is suitable).
- Contract manufacturing is permitted (For local manufacturing in China only).
Recently Proposed ‘priority review pathway’

- The China Food and Drug Administration (CFDA) recently released draft rules proposing a new priority review pathway of premarket submissions for certain medical devices with breakthrough technologies.

- This priority pathway builds upon the State Council’s Opinion on Reform of the Drug and Medical Device Approval System (“Document No. 44”), which was released in August 2015.

- While this new proposed priority review pathway shares many procedural characteristics with the innovative device pathway, the two procedures have different scopes.

- CFDA considers a device appropriate for this priority review pathway if it is classified as a Class III domestically manufactured device or a Class II or III imported device and it fulfils unmet clinical needs (especially for oncology, pediatric/geriatric and/or orphan diseases).

- CFDA has clarified in the Proposed Rules that if a device has already been accepted to the innovative device or emergency device review pathway, the device is not eligible for this new priority review procedure.
Conclusion

- The registration application under the ‘Green Channel’ has priority over other device applications in various respects, i.e., acceptance for evaluation, communications with CFDA, evaluation of clinical studies, and ultimately final approval by CFDA.

- The Special Procedures do not set forth a specific time frame according to which CFDA must ultimately approve the device for marketing. They only state that the device will be given priority.

- Despite the initial time and resources invested, the direct line of communication to CFDA throughout the application preparation and review process can be crucial in the race to commercialization.

- The chance to engage the regulator early in the design and innovation process can be highly valuable in the long run.

- Medical device companies doing business in China should monitor the implementation of these innovative pathways to determine whether it may provide an advantage to their products.