Summary of the clinical evaluation procedure for Class II & III Medical Device:

A. Clinical analysis and evaluation of the products listed in the catalogue of medical devices exempted from clinical trials.
B. Analysis and evaluation of the data obtained from clinical trials or clinical application of medical devices of the same type.
C. Analysis and evaluation through clinical trials.

A. Clinical analysis and evaluation of the products listed in the catalogue of medical devices exempted from clinical trials
   A1. Comparison between the relevant information about the product to be registered and the description in the “catalogue”.
   A2. Comparison between the product to be registered and the approved domestic medical devices in the “catalogue”. The comparison shall include a comparison table between the product to be registered and the approved domestic medical devices in the “catalogue”, and relevant supporting documents.
   A3. Providing proof that the product to be registered is equivalent to the products listed in the “catalogue”

Directory content

<table>
<thead>
<tr>
<th>No.</th>
<th>Product Name</th>
<th>Classification No.</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Paracentetic needle</td>
<td>6815</td>
<td>Consists of a needle tube and pipe. By using Seldinger techniques, the percutaneous entry pathway of the endovascular device was established. Seldinger refers to digital subtractionangiography in vascular puncture.</td>
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<td></td>
<td>Electronic endoscopy of UGI</td>
<td>6822</td>
<td>It is a soft electronic endoscope, generally consist of the head portion, a curved portion, and the insertion portion, and electrically connected to the light source. CCD head end portion of the received optical signals into electrical signals by the imaging system is observed on the display. Provided for viewing an image of the upper gastrointestinal tract (excluding duodenum), diagnosis, photography, video monitors.</td>
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<td></td>
<td>Analyzer of Mycobacterium Tuberculosis</td>
<td>6840</td>
<td>Usually consists of fixed barcode scanning system, image dialogue function LCD, test boxes, built-in system calibration of tube, the software and computer. By monitoring the microbial metabolic activity of CO₂ and O₂ to reflect the status of microbial growth, by monitoring gas change leads to the change of reflected light or excitation fluorescence of sensors, is captured by the photoelectric detector to read, analyze the growth of mycobacterium tuberculosis status. This product is used in the detection of mycobacterium tuberculosis and drug susceptibility test.</td>
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<tr>
<td></td>
<td>Hernia Repair Mesh</td>
<td>6846</td>
<td>It does not include the final full absorption of the product. Implantable flat sheet or folded from a flat sheet formed by combining network plug, generally made from polypropylene, polyethylene terephthalate made from polyester material, which may have a partially absorbing material. Working principle to fill the defect or play a bridging role in the organization. For abdominal hernia repair use.</td>
</tr>
</tbody>
</table>
Metal Nail of Femur Neck

The product structure refers to YY 0346. Made from Stainless Steel, Ti-alloy according with GB 4234, GB/T 13840, ISO 5832-1, and ISO 5832-3. Usually manufactured through normal machining operation, thermal treatment and surface processing (excluded 3D printing etc. innovative processing). Applicable for the internal fixation of the fracture of femoral neck.

B. Analysis and evaluation through the same type medical clinical data:

B1. Basis ideas and methods

Medical devices

Is there any difference with the equivalent medical devices?

No

Collect and analyse the clinical literature and/or clinical experience data of equivalent MD.

Generate the clinical evaluation report, and complete the clinical evaluation.

Yes

Prove that the difference will NOT have the negative impact to the safety and effectiveness of the product to be registered, by means of non-clinical research data, clinical paper data, clinical experience data as well as data of clinical trials conducted in China which focus on the difference.

No

The applicant should submit the corresponding clinical trials documents according to the regulations if product to be registered cannot be analyzed and evaluated through the data obtained from clinical trials or the clinical application of equivalent medical devices.
* The equivalent MD:
- An approved domestic medical device which is mainly the same as the product to be registered with regard to its working principle, structure and components, raw material (the material of the body-contacting part of the active medical device), manufacturing process, performance requirement, assessment of safety, applicable country/industrial standard, intention of use, etc.
- Mainly the same: the differences between the product to be registered and the equivalent medical devices will not negatively impact the safety and effectiveness of the product.

**B2. Comparison between the products declare and same medical device: (Active MD)**

1. Basic principle: 1) Principle of operation; 2) functional mechanism
2. Structure & Components: 1) Product composition 2) Core components
3. Manufacturing Processing
4. The raw material in contact with human body (such as material designation, animal-devolved materials, allogeneic material, ingredients, drugs, bioactive substance, conformed standard, etc. information)
5. Performance requirements: 1) performance data 2) function data
6. Safety evaluation (such as biocompatibility, biosafety, electric safety, radiation safety, etc.)
7. Software core functions
8. Conformed national/industrial standard
9. Application Scope: 1) target treatment group; 2) applicable parts; 3) contact methods to human body; 4) indications; 5) phase and level of the applicable diseases; 6) operation environment
10. Application method
11. Contraindications
12. Precaution and warnings
13. Sterilization/sterilization methods
14. Packing
15. Labeling
16. Instruction of use

**B3. Identification of the medical device of the same type**
1. When comparing the product to be registered with one or more medical devices of the same type, the comparison should include qualitative and quantitative data, verified and confirmed results.
2. It should be explained what is the same and what is different.
3. It should be verified and confirmed via the data of the product to be registered, in order to prove whether the difference will have the negative impact on the safety and effectiveness of the product.
4. A comparison with each kind of the same type of medical device should be included, but not be limited to the aspects listed below.

**B4. Collection of the clinical data**
1. Collect clinical data of the product to be registered: to prove the difference between the products to be registered and the medical device of the same type will not negative impact the safety and effectiveness of the product.
2. Collect clinical data of medical devices of the same type: to prove the safety and effectiveness of the product to be registered through the data obtained from clinical trials or clinical application of medical devices of the same type.

**B5. Analysis and evaluation of the clinical data**
1. Evaluation of the quality of the data
2. The establishment of the data
3. Statistical analysis of the data
4. Evaluation of the data
C. Clinical Trials

C1. The clinical trials on a medical device which will be conducted in China shall be conducted at a qualified clinical trial institution in accordance with the good clinical practices ("GCP") of medical devices and according with the Quality Management Specification for the Clinical Trial of medical devices. The registration applicant shall submit the clinical trial protocol and clinical trial report when applying for the registration.

C2. In conjunction with clinical trials of imported medical devices which are conducted overseas, the registration applicant may submit the clinical trial documents which were submitted to the authorities overseas, if the clinical trial meets the relevant regulations of China, technical requirements, such as the sample capacity, selection of the control group, evaluation index and principle, assessment of efficacy, etc. The clinical trial documents shall at least include the opinion of the Ethics Committee, clinical trial protocol and report. Supporting documents showing that there are differences in the clinical performance and/or safety of the products are nevertheless required.

C3. The medical devices listed in the catalogue of Class III medical devices require clinical trials that are conducted in China.

“Regulation” 22

22.1 Clinical trials shall be conducted for applications for the registration of Class II or III medical devices, unless the applicant may be exempted from clinical trials under any of the following circumstances:

- If the medical device under application has clear working mechanisms, finalized design and mature manufacturing processes, and will not change the general purposes of the medical devices of the same type that are available on the market and have been clinically used for years without any serious adverse effects having been recorded
- If the safety and effectiveness of the medical device under application can be proved by non-clinical evaluation; or
- If the safety and effectiveness of the medical device under application can be proved by non-clinical evaluation of the data obtained from clinical trials or clinical application of medical devices of the same type.

22.2 The catalogue of medical devices exempted from clinical trials shall be formulated, adjusted and published by the food and drug administration of the State Council.

“Act” Article 22
22.1 The products NOT listed in the catalogue of medical devices exempted from clinical trials.

22.2 If the safety and effectiveness of the medical device under application can be proved by analysis and evaluation of the data obtained from clinical trials or clinical application of medical devices of the same type.

22.3 The applicant may give some explanations when applying for the registration, and provide relevant supporting documents as evidence.