IMDRF International Medical Device Regulators Forum

Update on Medical Device regulatory in China

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CFDA

Key words

- Standard
- Classification
- Reform

The Provision for Medical Device Standards

CFDA Decree No.33

Published on 2017.4.17

In order to regulate the medical device standards administration,

1. Medical device standards include national and industry ,mandatory and recommended standards,
2. Medical device standards can be classified four types: Base、measure、management、product standard

   For example: Base standard-IEC 60601

   Management: ISO 13485

3.Procedure for standards development and revision, including time, public comments, published, abolishment

4.Review after 5 years in principal

5.Encourage the industry association and social organization draw up the organization standard

Classification catalogue for medical device

CFDA announcement 2017 No.104

Published on 2017.9.4

It is the base work for medical device administration.

high risk: 3 classification

moderate risk: 2 classification

low risk: I classification

Adjust the frame of classification catalogue

From 43 sub catalogue to 22 sub catalogue

- Reference to FDA classification system and the structure of catalogue for NB use in EU

- clinical use-oriented

- Add the indication and description for each medical device
- Medical device name example from 1008 to 6609
- Decrease 40 kinds of medical device classification, for example automatic immunofluorescence analyzer, silver amalgam from III to II

Medical device approval system reform

- Continue to push the work to development from 2015
- Next step: accept the clinical trials abroad, encourage the medical device industry innovation development….

including: revise the regulation, the provision and normati ve documents to support the reform to go further

International cooperation

- Prepare for the IMDRF rotating presidency in the 2018，
- Contribute to the Standards WG work, hold on the WG meeting in shanghai, discuss the next step work

Thank you

1.Regulated the medical device standards in China

2.Amended the classification catalogue of medical device

3.Continue to reform medical device review and approval system

Welcome to Shanghai