IMDRF International Medical Device Regulators Forum

Regulatory update on China Medical Device

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NMPA

Revised

Regulation on medical device supervision and administration （State council degree No. 680）

According to the legislative procedure, the Ministry of Justice are reviewing the draft.

the regulation is the base medical device regulation in China, and a series of provisions will follow to be revised.

UDI implementation

- NMPA issued the UDI system rules(2019,No.66)
- NMPA and MoH issued the UDI pilot work progr am

- Pilot products:

High risk implants, such as the heart、brain implants、Prostheses, Interventional treatment medical device

- including manufacturer, sales enterprise, medical institution and healthy authorities

- Pilot period:2019.7-2020.7

E-RPS submission

Notice on medical device registration electronic submission implementation（2019 No.46）

Base on the RPS ToC guidance of IMDRF WG achievements

Start from 6/24

also accept the application through paper materials, but, from 10/31, the paper materials structure must be the same with the electronic submission materials.

AI guidance

The first guidance about AI medical device

National Drug supervision scientific action plan

AI medical device study item, CMDE response for the item

NMPA also set up AI medical device invention cooperation platform， include the clinical study organization, IT organization, and so on

Recently, we have received some AI medical device registration application, maybe approve some products .

Custom-made medical device

NMPA MoH

provision on custom-made medical device administration

2019 No.53　2020.1.1 implementation

- for rare special illness condition
- no marketed medical devices are available
- manufacturer design and manufacture base on the medical institution special clinical needs
- for specific patient
- expect to improve the treatment effective

include medical device and IVD products

filing management

Thank you

1.Nothing is permanent except change.

2.NMPA change the regulation, the management system, for such purpose:

Make the patient to get the advanced medical device as soon as possible

Ensure the safety and efficiency of marketed medical device

Improve the harmonization of world medical device supervision and administration

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