IMDRF International Medical Device Regulators Forum

Update on China regulatory

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NMPA

Regulations on medical device supervision and administration

✓On June 1, 2021, the regulations on the supervision and administration of medical devices were officially implemented. The decree NO. is 739.

About 14 Provisions and The Normative documents need to be revised or draw up this year.

•The provisions for the medical device/IVD registration and filing

- The two provisions had been adopted by the State Administration for Market Regulation, officially issued on August 31 and officially implemented on October 1.
- there are 10 chapters and 124 articles in the provisions for the medical device registration and filing, 10 chapters and 125 articles in the provisions for the medical device registration and filing.
- Decree No. 43, 44

The two provisions carry out the reform requirements of the review and approval system, implement the four most stringent requirements, meet requirements of reform of government functions, optimize scientific and efficient review and approval procedures, and ensure the safety and effectiveness of medical device in China .

Main content:

1.Optimize the approval procedure and simplify the approval materials

2.Adopt the self-test report from the manufacturer

3.Optimize the clinical evaluation requirements, decrease the quantities of clinical trials.

4.Fully implement medical device MAH system, Strengthen the responsibilities and obligations of MAH

The MAH responsible for the safety and effectiveness of medical devices in the life cycle of development, production, sale and use according to the regulation.

5.improve the supervision efficiency

Establish professional inspector system, use UDI system to realize the traceability of products, and so on.

- **Covid-19 Epidemic prevention and control**

- Up to now, NMPA had approved 64 COVID-19 IVD kits, including 32 nucleic acid IVD kits, 29 antibody IVD kits and 3 antigen IVD kits. including 9 fast IVD kits(30min-1hour)

- NMPA will continue to strengthen the cooperation with WHO and other regulators， provide information on time.

Thank you

1. The Regulation on medical device supervision and administration had been official published.
2. The two provisions had been official published
3. Serve for Covid-19 Epidemic prevention and control