



IMDRF International Medical Device
Regulators Forum

Update on China Regulatory

Yuan Peng

NMPA

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Further optimization and adjustment of Medical Device Classification works in China

In July this year, the NMPA issued the "Opinions on Further Strengthening and Improving the Classification Management of Medical Device"

This document clarifies the next works in the classification of medical devices in China, mainly including five parts:

- Optimize the classification management system. Further clarify the responsibilities of the NMPA, Local MPA and the Medical Device Classification Technical Committee, improve the operational mechanism of the Classification Technical Committee, and improve the assessment and evaluation mechanism of experts and panels.
- The NMPA will consider to revise the "Classification Rules for Medical Devices" and based on the "Classification Rules for IVD", we will consider to revise the IVD classification catalogue, and we will establish a medical device classification and nomenclature database.

- Further clarify the application data requirements and review requirements for medical devices classification and consider to set up special procedures for special situations, such as public health emergencies. Implement dynamic adjustments to the classification catalog of medical devices.
- Focus on classification management policies research for new technology fields (previously, NMPA had issued the documents about the classification of AI medical devices), and strengthen research on medical devices classification work, and Increase training.
- Strengthen the construction of the medical device classification information system, optimize the workflow of online application and information query for medical device classification.
Open more about the classification information, ensure transparency in work

2023.8

Announcement on Adjusting Part of the Content of the Classification Catalogue of Medical Devices (No.101) related to 58 kinds of medical devices. for example: Ultrasound cutting hemostatic blade, ultrasound soft tissue surgical blade, ultrasound suction surgical blade, breast circumcision puncture needle and accessories, III level medical device.

<https://www.nmpa.gov.cn/ylqx/ylqxggtg/20230817153633135.html>

for more details

Promoting the Implementation of GB 9706 Standard in China

- GB 9706.1-2020 (Medical electrical equipment-Part 1:General requirements for basic safety and essential performance) equal to the IEC 60601-1-2012,MOD)
- 2020.4.9 the GB 9706.1-2020 had been published, as the mandatory national standards and will implement on 2023.5.1
- the medical device should comply with the general standards requirements after 2023.5.1, but if the medical device has the applicable special standards, it can comply with the general standards after the applicable special standards Implementation date.
- NMPA and SAMR(State Administration for Market Regulation) jointly released the notice on promoting the capacity of medical device test center, ensuring the Qualification Recognition of the New GB 9706 Series Standards

- from May 1, 2023, for the registration test application of the new GB 9706 series standards should be priority processing by medical device test center.
- The CNCA and related institutions shall carry out qualification recognition work related to the testing capabilities of the new GB 9706 series standards according to the application, accept and technical review of qualification recognition applications related to the testing capabilities of the new GB 9706 series standards priority.

Start to draw up the Medical Device management law

Open more about the classification information, ensure transparency in work

- On September 8th, the 14th Standing Committee of the National People's Congress issued a legislative plan, which included the Medical Device Management Law for the first time in the second level of "A draft law that needs to be urgently worked out and submitted for review when conditions are mature" projects.
- Regulations on the Supervision and Administration of Medical Devices(state council decree No.739), which is currently valid, was revised and issued in 2021, but as we know, there are still some issues that need to be revised in the regulations, such as the management of medical device standards
- NMPA has initiated a research project on issues related to the Medical Device Law, and preparing to draft
- This will be a long-term task, and there is no roadmap or timetable available currently, but NMPA hope to accelerate the process.

International Cooperation

- Strengthen cooperation with other countries and the IMDRF based on the GHWP platform
- On June 14, 2023, the GHWP Technical Committee held a regulatory meeting in Shenzhen, Guangdong Province, China. The GHWP chairman, Mr. Xu Jinghe, attended the opening meeting and delivered a speech.
- During the GHWP Technical Committee meeting, the NMPA and the Malaysian Medical Device Administration (MDA) held a medical device regulatory exchange meeting in Shenzhen
- Discuss with the IMDRF on how to strengthen cooperation between GHWP and the IMDRF

Conclusion

1. Further optimization and adjustment of Medical Device Classification works in China
2. Promoting the Implementation of GB 9706 Standard in China
3. Start to draw up the Medical Device management law
4. Strengthen cooperation with other countries and the IMDRF

Thank you/Questions

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