2018 Annual Report on China Medical Device Regulations

January, 2019

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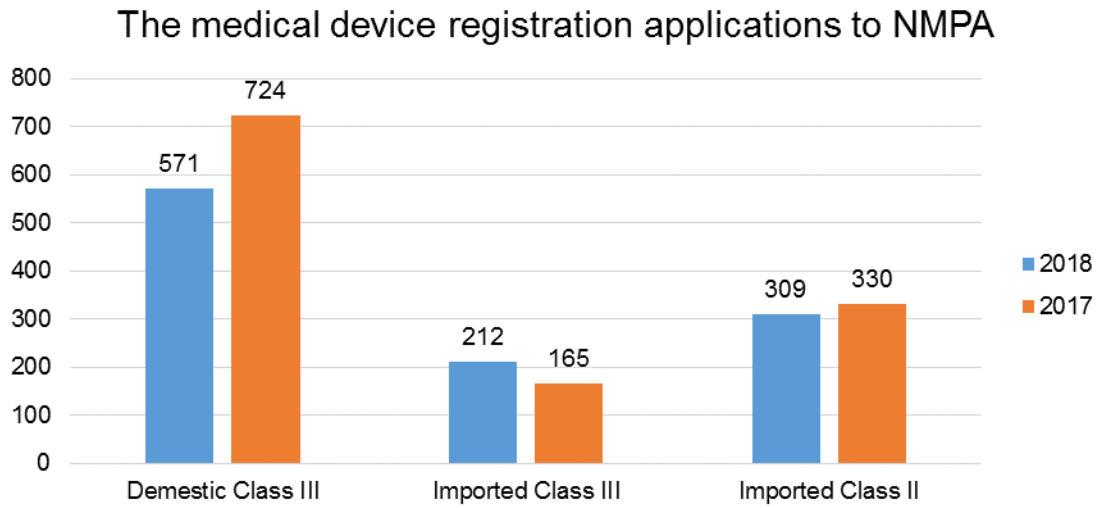
Contents

The report covers the most comprehensive regulatory changes in China's medical devices in 2018. We are concerned with the market access, registration, clinical trials, regulatory approval, sales, inspection and other aspects of medical devices. In the past year, many medical device regulations have been revised, and some regulations will take effect in 2019. China's medical device regulations are very complex, and we have selected the most influential data and regulations for overseas devices for analysis.

1. Registration and Approval Condition in 2018

As of the end of November 2018, National Medical Products Administration (NMPA) approved a total of 1,092 medical device products in 2018, a decrease of 9.9% over the same period in 2017. Among them, there are 571 Class III medical device products, 212 imported Class III medical device products, and 309 Class II medical device products.

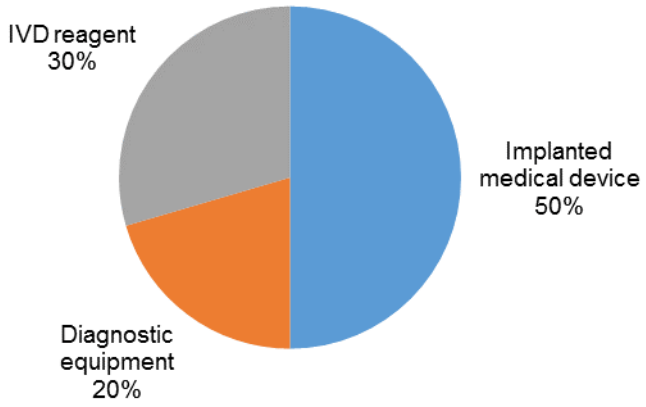


In 2018, 99 medical device industry standard revision projects were selected, and 104 medical device industry standards were reviewed and approved. By the end of 2018, there were 1,618 medical device standards in China, including 219 national standards and 1399 industry standards. In 2018, Center for Medical Device Evaluation (CMDE) issued a total of 61 guiding principles, of which 51 were formulated and 10 were revised. The consistency of medical device standards and international standards in China has reached more than 90%. The coverage and system of the standard system have been continuously strengthened, and the overall level of medical device standards has been continuously improved.

Since the release of the "Innovative Medical Device Special Approval Process", as of December 31, 2018, 197 products have entered the special review channel for innovative medical devices, approved neurosurgical navigation and positioning systems, positron emission tomography and magnetic resonance imaging. The system registered 54 products, from the type of approved products, 22 implanted medical devices, 9 diagnostic devices, and 13 IVD reagents. In 2018, the CMDE

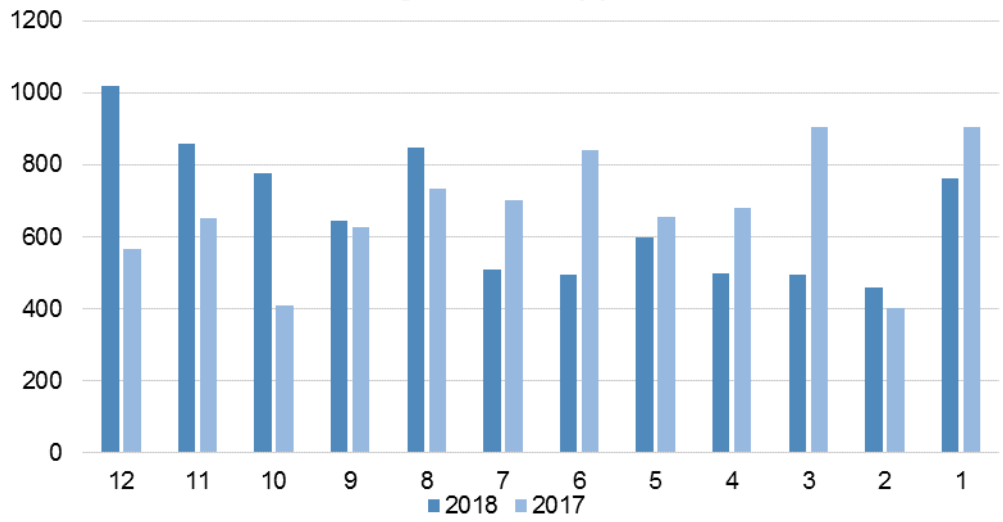
Innovative Medical Device Review Office received 316 innovation applications and approved 21 innovative medical devices. A group of innovative products with strong innovation, high technology content and urgent clinical demand went on the market, filling the gaps in related fields and better meeting the health needs of the people.

China Innovative Medical Device Approval



In 2018, CMDE accepted a total of 7960 applications for registration, a decrease of 1.49% compared with 8080 in 2017. CMDE issued a total of 885 registration quality management system verification notices, and the priority approval medical equipment audit office received 36 priority approval applications, and agreed to give priority to 11 approvals.

The number of registration applications to CMDE



In order to strengthen the supervision and management of medical equipment quality and ensure the safe and effective use of medical device products, in 2018, NMPA organized a total of 3,592 batches of 110 varieties of medical equipment supervised in