The Regulations on Supervision and Administration of Medical Devices was amended and promulgated by the State Council on March 7th, 2014, effective June 1st, 2014. The last version is from 2000. The following highlights the changes that have been made.

A. Filing/Registration for Medical Device Product:

1. The requirements for Class 1 medical devices (medical devices with low risks and their safety and effectiveness can be ensured through routine administration) have been reduced to filing as opposed to district FDA registration approval.

2. The official approval time is now 23 working days for approvals, regardless of the level. This approval time does not include the experts’ assessment period. The former approval times were 30 working days for district level approval, 60 working days for municipal/provincial level and 90 working days for state level. The validity term of the registration certificate is extended from four years to five years and extension application will not be approved if such application is submitted after expiration.

3. Filing for clinical trial or test for Class 2 (medical devices with middle risks and their safety and effectiveness need to be strictly controlled) and Class 3
(medical devices with high risks and their safety and effectiveness need to be strictly controlled by special means) is mandatory. The applicant must file with its local FDA for its clinical trial or test, and the local FDA must notify the responsible FDA of the medical institutions who will perform clinical trial or test. For the clinical trial or test for Class 3, preliminary approval of SFDA must be obtained before starting.

B. **Filing/Registration for Medical Device Production**

1. The registration requirement for enterprise producing medical device of Class 1 with municipal/provincial FDA has been changed to mandatory filing with district FDA.

2. The implanted medical devices with high risks are prohibited from subcontracted production, which in the past did not have such a restriction.

C. **Filing/Registration for Medical Device Marketing**

1. Sale of Class 1 medical devices is released from the requirement to file with municipal/provincial FDA and changed to free marketing category.

2. Sale of Class 2 medical devices has been changed from registration with municipal/provincial FDA to filing with district FDA and no *Medical Device Marketing Enterprise License* will be issued.

3. Sale of Class 3 medical devices has been changed from registration with municipal/provincial FDA to registration with district FDA and the *Medical Device Marketing Enterprise License* with five year validity term will be issued.

D. **Medical Device User:** There aren’t any requirements on medical device users in the past, but in the new regulation, the following provisions are provided:

1. Before purchasing medical devices, the using enterprise must ensure that the medical device to be purchased has official qualification certificates and the device provider is officially authorized.

2. Medical device using enterprise must set up formal records for its inspections of the medical devices and for information about the medical devices it purchases.

3. Medical device using enterprise must have proper storage place and conditions for its medical devices purchased;

4. Medical device using enterprise must properly handle the issue of re-usage of the medical devices in accordance with related state regulations on disinfection and management. Disposable devices cannot be reused and should be destroyed and records should be kept in accordance with state regulations.

5. Medical device using enterprise must ensure that its medical devices work...
properly and keep formal records for using, maintenance, transfer and actual service life of each large scaled medical device for at least five years past the expiration of the official service life of the medical device.

6. Medical device using enterprise must properly keep the original documents for purchasing Class 3 medical devices. For large-scaled and implanted medical devices, the using enterprise must provide information from the diagnosis records of the patients that indicates name, key technical specifications and the consequences related to the usage of the medical devices.

7. Medical using enterprise is prohibited from using unregistered, unqualified, expired, invalid and obsolete medical devices.

8. Medical using enterprise is prohibited from transferring expired, invalid, obsolete and unqualified medical devices.

E. Handling of Adverse Events and Recall of Medical Devices

The new regulation has some provisions on issues related to adverse handling and medical device recalls, for example the state will establish a monitoring system for adverse events to assess and publish the adverse results of these events to the public, and medical device production, marketing and using enterprises are also required to monitor and report their own adverse events; Medical device production and marketing enterprises need to inform related parties including medical device users once they find the medical device fails to satisfy the compulsory standards and has defects and such enterprises also need to report such un-commitment to FDA, recall their products and keep good records.

F. Punishment

The new regulation has more severe punishments for violations. For example, for producing or marketing medical devices without licenses, the punishment is raised from the previous 3-5 times of the illegal income to 5-10 times provided its illegal income is more than RMB10K and from RMB10K-30K to RMB50K-100K provided the illegal income is less than RMB10K; and for providing fake application documents, the applicant is not allowed to apply for filing/registration within 5 fives.

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