CFDA urgent update: feedback to the revised medical equipment classification catalog due November 25th, 2016.

Reminder to the submission deadline on State Food and Drug Administration "Catalog on the medical device classification (revised) feedback letter" due November 25, 2016.

The revised medical device classification catalog has significant implications for medical devices registrations or renewals. If your devices are not included in the revised catalog, you have go through the expert panel forum which is time-consuming and costly.

This newly released revised draft catalog for feedback has been in the works for the past seven years. It was finally released for industry feedback. The previous catalog was released in 2002. It is very dated and lacks details and clarity. It fails to keep up with the rapid proliferation of medical devices and the growth of complex technologies that have taken place in China.

The revised catalog has 22 subdirectories. It consolidated and reduced the 2002 version’s 43 subdirectories by 19. Under each of the 22 subdirectories, there are further detailed divisions. Here are a few examples of how to look at the categories.

1. Surgical instruments category has four sub-categories:
   1. surgical instruments with electronics (active)
   2. surgical instruments without electronics (passive)
   3. nerve and vascular surgical instruments: contacts with nerve and vascular type of equipment have special requirements so it has its category.
   4. orthopedic surgery-related devices: due to its complexity, high volume and a wide range of products, it has its own category.
2. Devices with electronics appeared in 8 different categories primarily:
   1. radiation therapy equipment
   2. medical imaging equipment
   3. medical examination and monitoring equipment
   4. respiratory, anesthesia and first-aid equipment.
   5. physical therapy equipment
   6. blood transfusion, dialysis and cardiopulmonary bypass equipment
   7. medical equipment disinfection and sterilization equipment
   8. active implant device.
3. Devices without electronics appeared in 3 different categories primarily:
   1. Passive implant devices
   2. infusion, care and protective equipment
   3. patient-carrying devices
4. Devices by clinical departments:
   1. ophthalmic devices
   2. dental instruments
   3. Obstetrics and Gynecology, reproductive and contraceptive devices.

It is worth pointing out that Medical Software has its own category for independent operating software, different from the sub-directory of medical independent software products.

CFDA needs the feedback before November 25, 2016. Please make sure that your products are reflected in the categories. If you need to provide feedback to CFDA, please let us know and we will consolidate and send it for you. Please email to info@chinameddevice.com

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