ROPES & GRAY ALERT

China Life Sciences

September 8, 2017

China FDA Updates the Medical Device Classification Catalogue

Attorneys
Katherine Wang

On August 31, 2017, the China Food and Drug Administration ("CFDA") announced the final revision to the 2002 Medical Device Classification Catalogue ("2002 Catalogue"). The revised version ("New Catalogue"), which will become effective on August 1, 2018, updates the device classification significantly and will have considerable impact on device registration, manufacturing and distribution. Device companies will need to check their current product portfolio against the New Catalogue and develop transitional plans before the effective date if any of their devices will be reclassified.

In China, medical devices are divided into three regulatory classes based on the identified risks associated with the devices. The level of regulatory control will be the highest if the devices are classified as Class III. Device applicants can determine the class of their devices by using the classification catalogue, CFDA's device classification notices, and classification rules for medical devices issued by CFDA in 2015. In addition, applicants can submit device classification applications to seek classification determination opinions for any new devices not covered by the catalogue or notices. Therefore, the New Catalogue, which is more comprehensive than the 2002 Catalogue, will provide clear guidance to device applicants determining the level of regulatory control for their devices.

Compared with the 2002 Catalogue, the New Catalogue introduces the following changes:

a. Reduces the number of device catalogues to 22 from the current 43 based on the functions and clinical uses of the medical devices. For each catalogue, the New Catalogue contains primary type, sub-type, device description, intended use, device examples and classification (I, II & III).

b. Reclassifies the current 260 device types into 206 primary types, and further subdivides the 206 primary types into 1,157 sub-types of products.

c. Adds a detailed description of the device features and intended uses for each sub-type. This change would provide clear guidance to device applicants who want to classify a specific device.

d. Includes 6,609 example devices in the device example column, whilst the 2002 Catalogue only listed 1,008 example devices.

e. Down-classifies 40 devices to Class II (e.g., fully automated immunodiagnostic system, fully automated disposable biopsy needle) or Class I (e.g., orthodontics spring).

f. Up-classifies certain types of devices to Class III (e.g., automated blood bank system, active breathing coordinator).

It is worth pointing out that the New Catalogue does not cover classification catalogues for in vitro diagnostic reagents ("IVD"). Companies should refer to the specialized IVD sub-catalogue issued by CFDA in 2013 and relevant scattered CFDA notices when determining the classification for their IVD. In addition, the New Catalogue is not applicable to any combination device products.

Following the issuance of the New Catalogue, CFDA has announced a circular (CFDA Order [2017] No.143) to instruct device companies how to adapt to the reclassification issues arisen from the New Catalogue during device registration application and renewal process. We recommend that any device companies affected by the New Catalogue make plans as required by this circular.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.