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China Releases New Notification Procedures for Class I Medical Devices

Article By:

John C. Balzano

The China Food and Drug Administration (CFDA) issued a Notice on Items Related to Class I Medical Device Notifications (Notice) to establish new notification procedures for Class I medical devices, which includes in vitro diagnostics. This Notice is one of several that CFDA issued at the end of May 2014 related to the implementation of its recently completely revised Medical Device Supervision and Administration Regulation (MDR), which became effective on June 1, 2014.

The revised MDR changed the procedure for placing a Class I medical device on the market from a registration procedure to a government notification procedure. According to the Notice, both import and domestic manufacturers may now submit materials via a new form (which was attached to the Notice). Once submitted, a municipal food and drug regulatory authority (for domestically manufactured devices) or CFDA (for imported devices) will make an "on the spot" determination as to the completeness of those materials. If the submission is complete, then the Agency will issue a notification certificate, and the device may be placed on the market. If the Agency rejects the submission and requires additional materials, it will explain its reasons for doing so. CFDA will also publish basic information contained in the notification on its website.

For Class I devices that that have already been registered under registration procedures prior to the implementation of the revised MDR in June 2014, the applicant must complete notification procedures prior to the expiration of the registration. If the device is no longer considered a Class I device according to theclassification catalogue, which was recently released by CFDA, then the manufacturer will need to follow separate procedures to re-register the device as a Class II or Class III device, as the case may be.

If CFDA or the municipal food and drug regulatory authority has already accepted an application for registration of the device submitted prior to June 2014, the applicant should withdraw the application. The Notice states that regulatory authorities will not review these applications. The applicant should then refile through the notification procedures.

CFDA has been using these types of notices, which it does not put through the normal notice and comment process, instead of issuing new and more comprehensive implementation regulations for the MDR. The Agency had published proposed implementation regulations in March 2014, but it has not yet finalized them. Medical device manufacturers doing business in China should continue to

monitor for notices of this sort that might be issued by CFDA, as well as for more comprehensive implementation regulations for the revised MDR.

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