Medical Device Update: FDA Issues Proposed Regulations on Medical Device Classification and Reclassification to Streamline the Process

The Food and Drug Administration (FDA) issued proposed regulations on March 25, 2014 to implement Food and Drug Administration Safety and Innovation Act (FDASIA) provisions enacted in July 2012 on medical device classification and reclassification.[1] The FDASIA provisions and the proposed regulations are intended to streamline the process for device reclassification by changing the reclassification process from notice-and-comment rulemaking to administrative order. Importantly, the revised classification procedure applies to both "up classification" (e.g., Class II to III) and "down classification" (e.g., Class III to II) of devices and, thus, could lead to a more expedited reclassification of higher-risk devices from Class II to Class III, with reduced public dialogue.

Due, in part, to congressional and industry concerns regarding the FDA's slow-paced reclassification of "preamendments devices" (i.e., those marketed prior to the Medical Device Amendments of 1976), FDASIA changed the reclassification procedure from a rulemaking process to an administrative order process.[2] By eliminating the rulemaking requirement, the FDA is not required to analyze the economic and other impacts of reclassification, as required by executive orders, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995. These impact analyses were believed to be a source of delay in the reclassification process.

Devices subject to possible reclassification include the following:

- Devices for which there is "new information" supporting a reclassification (section 513(e) of the Federal Food, Drug, and Cosmetic Act [FFDCA])
- Devices that were marketed prior to May 28, 1976 (i.e., preamendments devices) that were classified into Class III, but for which the FDA has not yet required submission of a premarket approval application (section 515 (b) of the FFDCA)
- Devices that were not marketed prior to May 28, 1976 and are classified automatically as Class III, unless and until the FDA issues an order classifying the device into Class I or II or issues an order finding the device substantially equivalent to a predicate device that does not require the filing of a premarket approval application (section 513(f) of the FFDCA)

Under FDASIA, the following steps must be adhered to in order to obtain reclassification of a device:

- Publication of a proposed order in the *Federal Register*, which includes the proposed reclassification and a summary of the valid scientific evidence that supports the reclassification
- Conduct of a device classification panel meeting, either before or after the proposed order has published
- Consideration of comments submitted to the relevant public docket
- Issuance of a final order

If reclassifying from Class II to Class III, the proposed order must explain why general and special controls are insufficient to provide reasonable assurance of safety and effectiveness, and, when reclassifying from Class III to Class II, the proposed order must explain why general and special controls are sufficient to provide reasonable assurance of safety and effectiveness.

Although not addressed in FDASIA, the FDA has also proposed new regulatory definitions for Class I, Class II, and Class III devices (proposed 21 C.F.R. § 860.3). FDA notes that the current statutory definition of Class III

1. 79 Fed. Reg. 16252 (Mar. 25, 2014).

2. Section 608 of the Food and Drug Safety and Innovation Act, amending sections 513(e) and 515(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 360c(e) and 360e(b).

devices reserves this class of products to devices "that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury," in other words, high-risk devices.[3] The current regulatory definition,[4] however, does not explain which high-risk devices will be classified as Class III because the FDA determines there is insufficient information to determine what general and special controls would provide reasonable assurance of safety and effectiveness. Accordingly, in the proposed definition of Class III, the FDA lists five device categories for which it may find there is not adequate information to determine that general and/or special controls are sufficient to provide reasonable assurance of a device's safety and effectiveness. These device categories are as follows:

- Devices that present known risks that cannot be controlled
- Devices for which the risk-benefit profile is unknown or unfavorable
- Devices for which a full review of manufacturing information is necessary
- Devices for which review of a supplemental application for a change affecting safety or effectiveness is necessary to provide reasonable assurance of safety and effectiveness
- Combination products (where the device provides the primary mode of action and the drug constituent requires a finding that it is safe and effective or the biological product requires a finding that it is safe, pure, and potent)

In addition to accelerating the ongoing reclassification of preamendments devices, the more streamlined reclassification process may allow the FDA to more quickly address device categories that are determined to present a high risk. For example, the FDA has proposed to reclassify automated, external defibrillators from Class II to Class III. Up-classification of devices is more likely to be affected by the streamlined process than down-classification, because, generally, the up-classification process involves a more significant review of the economic impact and other impact analyses required for rulemaking.

To ensure that the FDA does not up-classify devices without giving appropriate consideration to all relevant risk-benefit factors, the proposed regulation requires that a panel meeting be held before a final reclassification order is published. However, manufacturers should be aware that, although a panel review may potentially slow down an undesired up-classification review, some commentators have expressed concern that a panel review could also negate the efficiency benefits of the administrative order process during a down-classification or facilitate FDA action in the face of opposition.

Comments may be submitted on the proposed rule until June 23, 2014.

Contacts

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3. Section 515(a)(1)(C) of FFDCA, 21 U.S.C. § 360c(a)(1)(C).
4. 21 C.F.R. § 860.3.