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ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule On Reclassifying Medical Devices

March 24, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA Safety and Innovation Act (FDASIA), enacted in July 2012, amended the Food, Drug & Cosmetic Act (FDC Act) to allow FDA to reclassify medical devices by administrative order instead of the cumbersome rulemaking process.

The FDC Act establishes the following three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls), and class III (premarket approval). Under the FDC Act, devices that were in commercial distribution before the enactment of the 1976 amendments are classified after FDA has: (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

The FDC Act provides that FDA may, by administrative order published in the Federal Register, reclassify a device based upon "new information." FDA can initiate a reclassification, or an interested person may petition FDA to reclassify a device. The term "new information," as used in the FDC Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time.

FDASIA changes the procedure to reclassify a device under the FDC Act. Under the new procedures, when FDA reclassifies devices, it must do so through administrative order. Prior to the publication of a final order, FDA must also publish a proposed order in the Federal Register and consider any comments submitted on the proposed order. FDA must, in addition, hold a device classification panel meeting. The panel meeting must occur before the final order is published, and may occur either before or after the proposed order is published. The proposed order must include the following: (1) A substantive summary of valid scientific evidence, including the public health benefits and risks of the device; (2) when reclassifying from class II to class III, an explanation that general and special controls are insufficient to reasonably assure safety and effectiveness; and, (3) when reclassifying from class III to class II, an explanation that general and special controls are sufficient to reasonably assure safety and effectiveness.

Further, the proposed regulation would identify five categories of devices for classification into class III based on the risks, benefits and available controls for the three device classes:

RELATED PEOPLE

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RELATED PRACTICE AREAS

Food, Drug and Device Law

- 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 premarket review of any change affecting safety or effectiveness is necessary
- Combination products (where the primary mode of action for combination includes a drug for which a finding is required that the drug is safe and effective or a biological product for which a finding is required that it is safe, pure, and potent

The lengthy proposed regulation addresses other aspects of device classification as well, and a copy may be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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