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Food, Drug And Device Law Alert - FDA Issues Amended Final Guidance On Medical Device Accessories

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The Food and Drug Administration (FDA) issued several medical device guidance documents late last year, including an amended version of a previously final guidance titled "Medical Device Accessories: Defining Accessories and Classification Pathways." The FDA revised the guidance in response to the FDA Reauthorization Act of 2017, which required the agency to "classify an accessory under [section 513 of the Food, Drug & Cosmetic (FD&C) Act] based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used."

The background section of the guidance notes that the FDA has traditionally classified accessories in one of two ways:

1. By including the accessory in the same class as the parent device in one of three ways:

- Through a 510(k) clearance
- Through a Premarket Application (PMA) approval
- Through including it in the classification regulation or order for the parent device

2. By issuing a separate classification regulation or order for the accessory

The guidance focuses on the Accessory Classification process described in Section 513(f)(6) of the FD&C Act. For example, the de novo classification process may be used for a new accessory type (i.e., an accessory of a type that has not been previously classified, cleared for marketing under a 510(k) submission, or approved in a PMA). In addition, manufacturers of accessories within an accessory type that has already been classified by regulation or order, or has received PMA approval or 510(k) clearance, may seek reclassification or exemption from the requirement to submit a 510(k) notification.

The guidance states that FDA asks two questions when determining whether a device is an accessory: (1) Is the device intended for use with one or more parent devices? and (2) Is the device intended to support, supplement, or augment the performance of one or more parent devices? The answer to the first question "will generally be determined by the

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labeling and promotional materials for the potential accessory…," according to the guidance. To help answer the second question, the guidance includes the following definitions and offers at least one example for each term:

- Supports – enables or facilitates a parent device to perform according to its intended use
- Supplements – adds a new function or new way of using the parent device, without changing the intended use of the parent device
- Augments – enables the patent device to perform its intended use more safely or effectively

Signaling a departure from its traditional way of classifying accessories as described in the background section, the FDA states that it "intends to determine the risk of accessories and the controls necessary to provide a reasonable assurance of safety and effectiveness according to their intended use" just as it does for non-accessory devices. The guidance is explicit that accessories will not automatically be placed in the same class as their parent device(s): "the risk profile of an accessory can differ significantly from that of the parent device, warranting differences in regulatory classification."

The guidance includes a description of the process for requesting regulatory classification of an accessory. In the final section of the draft guidance, the FDA encourages firms to use the de novo classification process when seeking classification decisions for new types of accessories. This process can lead to a Class I or Class II classification, even in the absence of a legally-marketed predicate device, and thus avoid an automatic Class III classification and the associated need to follow the more expensive and time-consuming premarket approval process.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug and Device Practice Group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.

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