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Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Medical Device Accessories

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The Food and Drug Administration (FDA) recently issued a draft guidance document titled, “Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types.” According to the FDA, the draft guidance “is intended to clarify and modify FDA’s policy concerning the classification of accessories” and to discuss the application of that policy to specific categories of accessories.

The background section of the draft guidance notes that FDA has traditionally classified accessories in one of two ways: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

    a. Through a 510(k) clearance

    b. Through a PMA approval

    c. 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The draft guidance states that FDA asks two questions when determining whether a device is an accessory: (1) Is the device intended for use with one or more parent devices?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 labeling and promotional materials for the potential accessory….” To help answer the second question, the draft guidance includes the following definitions:

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

The draft guidance offers at least one example for each term.

Signaling a departure from its traditional way of classifying accessories as described in the background section, the FDA next states that it “intends to determine the risk of accessories and the controls necessary to provide

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a reasonable assurance of safety and effectiveness according to their intended use" just as it does for non-accessory devices. The draft guidance is explicit that accessories will not automatically be placed in the same class as their parent device(s): "the risk profile of an accessory can differ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."

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.

A copy of the draft guidance can be found here.

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