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Important Considerations for Defining Medical Device Accessories and Classification Pathway for New Accessory Types

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Introduction

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) have issued the draft guidance, "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types." [1]

According to the draft guidance, the FDA will adopt an accessory classification policy which includes determining (a) if the article meets the definition of an accessory, (b) the risk of the accessory when used as intended by the manufacturer with the parent medical devices and what regulatory controls are necessary to provide a reasonable assurance of safety and effectiveness and (c) accessory classification through the *de novo* [2] process.

This is an important draft guidance to stakeholders. It clarifies how the FDA's traditional risk- and regulatory control-based classification approach applies to a medical device accessory, and helps stakeholders understand how the FDA may evaluate such devices going forward. Because the FDA follows a risk- and regulatory control-based classification approach, risks associated with an accessory are those it presents when used with the parent device as intended by the manufacturer. The manufacturer's intention is manifested in its labeling and promotional material for the parent device.

The draft guidance:

- Clarifies what the FDA considers when determining the risk of a device accessory and its risk-classification policy.
- Provides definitions for "accessory" and "parent device."
- Contains a checklist for the information required in support of a *de novo* submission.
- Includes — most importantly for manufacturers — guidance on when the FDA would:
    - Designate a low-risk accessory Class 3 simply because it supports, supplements and/or augments the performance of a Class 3 parent device.
    - Evaluate the accessory based on its inherent risks.
- Helps manufacturers bring accessories to market faster than parent devices.

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Background

As provisioned in the Federal Food, Drug, and Cosmetic (FD&C) Act, the term "medical device" also includes the term "accessory." Per Section 201(h) of the FD&C Act, a medical device is:

> "An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory, which is:
>
> a) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> c) intended to affect the structure of any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Compared to the FD&C definition above, the draft guidance defines an accessory as:

> "a device that is intended to support, supplement, and/or augment the performance of one or more parent devices."

The draft guidance defines a parent device as:

> "a finished device whose performance is supported, supplemented, and/or augmented by one or more accessories."

The definitions above are important because they form the basis for how the FDA analyzes an accessory for the risk classification process.

Under the traditional approach — which many in the device industry are familiar with — the FDA has classified an accessory in the following two ways:

- First, by adopting the same classification as the parent device under various regulatory pathways. Under the premarket notification or 510(k) pathway, typically an accessory to a cleared device inherited the same risk classification as the cleared parent device. Under a premarket approval (PMA) application or pathway, an accessory to the approved Class 3 device also typically inherited the Class 3 designation of the parent device. However, under certain circumstances, the FDA classified an accessory by following a different risk-based classification approach for accessories, which sometimes landed the accessory in the same classification as the parent device, and other times in a different classification altogether.
- Second, by issuing a unique and separate classification for the accessory when the FDA determined it appropriate to do so. This type of risk classification was typically considered for those accessories with more ubiquitous functionalities and served numerous types of medical devices or had unique stand-alone features.

Draft Guidance Definitions

Accessory: "A device that is intended to support, supplement, and/or augment the performance of one or more parent devices."

Parent Device: "a finished device whose performance is supported, supplemented, and/or augmented by one or more accessories."

Conclusion

Under the new approach, an article must meet the definition of an accessory for the FDA to start considering a risk-based classification evaluation. An article that does not meet the definition of an accessory will not be considered one by the FDA, even if the accessory device is used with a medical device. For example, by simply residing on a smartphone, a mobile medical application (MMA) does not convert the smartphone into an accessory device. The smartphone is a general handheld platform able to host an array of applications, including an MMA.

The FDA may classify an individual accessory per the regulation governing its parent device by determining which regulatory controls are necessary to provide reasonable safety assurance and effectiveness, or via a risk-based classification process independently through the *de novo* pathway.

References

1. FDA, Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf

2. Per FD&C ACT Section 513(f)(2), the *de novo* process allows for a risk-based regulatory pathway to Class 1 or Class 2 designation for accessories. Such a designation is possible when the FDA deems that general controls or general and special controls for the new type of accessory provide reasonable assurance of safety and effectiveness, and for which there is no legally marketed predicate device. If granted a *de novo*, the new accessory may be marketed as a Class 1 or Class 1 device and serve as a predicate device for future premarket notifications. If declined a *de novo*, the accessory remains designated in Class 3 and may not be marketed.

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