FDA Issues Draft Guidance on Medical Device Accessories

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On January 16, 2015, the Food and Drug Administration (FDA) issued a draft guidance document titled "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types."[1] The draft guidance proposes delinking a new device accessory's risk classification from the risk classification of the parent device, and invites manufacturers to use the *de novo* classification pathway to request risk-based classifications for accessories of a new type. The draft guidance defines an accessory as a device that:

1. Is intended for use with one or more parent devices, and
2. Is intended to support, supplement, and/or augment the performance of one or more parent devices.

Although the draft guidance does not establish legally enforceable responsibilities, it is possible that FDA will begin assigning lower risk classification to accessories through the *de novo* pathway before the final guidance is issued. Under the process, a company may request a Class II or Class I risk classification for its new device,[2] and substantiate the request with appropriate evidence regarding the risk posed by the device and the necessary controls. While the *de novo* pathway shifts some of the burden of risk evaluation to the applicant, it also allows companies to argue for an appropriate classification and controls for their devices.

Background

The draft guidance emerged from FDA's ongoing development of a regulatory framework for the regulation of software. In April 2014, the Health IT Committee FDASIA Workgroup, which included representatives from FDA, the Office of the National Coordinator for Health Information Technology, the Federal Communications Commission, and private industry stakeholders, requested that FDA provide greater clarity related to several aspects of medical device regulation involving health IT, including:

1. The distinction between wellness and disease-related claims;
2. Medical device accessories;
3. Medical device clinical decision support software;
4. Medical device software modules;
5. and Mobile medical apps.

The draft guidance on medical device accessories appears to be FDA's response to the second item on the Workgroup's list.[3] In the context of the FDASIA Health IT report, the draft guidance on medical device accessories separates the risk classification process for accessories from risk classification for parent devices. This approach to the regulation of device accessories allows the agency to tailor its regulation to the gadgets and software proliferating in the medical and wellness fields.

Summary of the Draft Guidance

The draft guidance proposes to permit device accessories to be classified at a lower risk than their parent devices, using the *de novo* process. FDA fleshes out the definition of a device accessory, establishing that an accessory device is an article with one of two intended uses. The first category comprises articles intended for use with one or more parent devices. The agency will examine labeling and promotional materials to determine whether an article is intended to use with a parent device. Notably, an article would not meet the definition of an accessory device simply because it may be used in conjunction with a device.

The second category comprises articles intended to support, supplement, and/or augment the performance of one or more parent devices. The draft guidance defines "support" as enabling or facilitating the parent device to perform according to its intended use. "Supplementing" is defined as adding a new function or a new way of using the parent device, without changing the intended use of the parent device. Finally, "augmenting the performance" is defined as enabling the device to perform its intended use more safely or effectively.

In addition to defining what a device accessory is, the draft guidance briefly discusses the risk classification process for accessories. FDA proposes to determine the risk of accessories when used, as intended, with the parent device type; and acknowledges that the risk profile of an accessory can differ significantly from that of the parent device. FDA would evaluate the risk imposed by the accessory's effect on the parent device and any unique risks of the accessory independent of its parent device.

Finally, FDA encourages manufacturers to use the *de novo* classification process in Section 513(f)(2) of the Food, Drug, and Cosmetic Act to request risk-based classifications of new types of accessories. The draft guidance outlines the *de novo* pathway procedures in an appendix.

Conclusion

FDA's draft guidance takes a step toward lowering regulatory requirements for device accessories, including software and hardware accessories. Manufacturers and other stakeholders are encouraged to comment on the draft to identify areas of agreement and disagreement, and to request additional clarification. For example, stakeholders may propose specific categories of accessories that would be classified as Class I devices without applying through the *de novo* pathway. Comments are due on April 20, 2015.

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1. Available here.↩

2. That is, a device for which there is no appropriate predicate device, to which the new device is substantially equivalent.↩

3. Concurrently with the guidance on medical device accessories, FDA issued a draft guidance titled "General Wellness: Policy for Low Risk Devices", addressing the first item on the list as well.↩

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