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# Client Alert

FDA & Life Sciences Practice Group

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## FDA Issues Draft Guidance on Medical Device Accessories

On January 20, 2015, the U.S. Food and Drug Administration (FDA) issued a draft guidance document titled *Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types (January 20, 2015)* ("Draft Accessory Guidance").[1] The Draft Accessory Guidance provides FDA's proposed definition of an accessory and explains the agency's process and proposal for classifying medical device accessories. Comments on the draft guidance may be submitted to **www.regulations.gov** until April 20, 2015 and should reference docket number FDA-2015-D-0025-0001.

### What is an Accessory?

In the draft guidance, FDA defines an accessory as "a device that is intended to support, supplement, and/or augment the performance of one or more parent devices."[2] A parent device is defined as "a finished device whose performance is supported, supplemented, and/or augmented by one or more accessories."[3] FDA further explains that determination of whether a product is intended for use with one or more parent devices will be based on the labeling and promotional materials of the product (i.e., the potential accessory) rather than the labeling and promotional materials of the parent device.

The Draft Accessory Guidance also explains when a device is intended to support, supplement or augment a parent device. A device "*supports* the performance of a parent device by enabling or facilitating the device to perform according to its intended uses"[4] (*e.g.*, a rechargeable battery used with an automated external defibrillator)." A device "*supplements* the performance of a parent device if it adds a new function or new way of using the parent device without changing the intended use of the parent device"[5] (e.g., a balloon catheter used to insert a heart valve). Finally, a device "*augments* the performance of a parent device by enabling the device to perform its intended use more safely or effectively"[6] (e.g. guidewire used with a bone-cutting saw increases the precision of the parent device).

For more information, contact:

**Pamela F. Forrest**
+1 202 661 7888
pforrest@kslaw.com

**Elaine H. Tseng**
+1 415 318 1240
etseng@kslaw.com

**Quynh T. Hoang**
+ 1 202 626 2939
qhoang@kslaw.com

**Lynette A. Zentgraft**
+ 1 202 626 2996
lzentgraft@kslaw.com

**King & Spalding**

***Washington, D.C.***
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

***San Francisco***
101 Second Street
Suite 2300
San Francisco, CA 94105
Tel: +1 415 318 1200
Fax: +1 415 318 1300

**www.kslaw.com**

**Classification of Accessories**

The draft guidance explains the current process by which accessories are classified:

• ***Through the 510(k) process***. In these cases, the classification regulation only identifies the parent device; however, through the 510(k) submission, FDA finds accessories to the parent to be substantially equivalent. As such, the accessories take on the same regulation as the parent device.

• ***Through the PMA process***. Accessories to PMA approved devices "may also be approved in the PMA, in which case they would remain in class III along with the parent device."[7]

• ***Express inclusion of accessories in the classification regulation or order for the parent***. Under these circumstances, the classification regulation specifically cites both the parent device and corresponding accessories. Under these circumstances, the accessories are typically placed in the same class as the parent device; however, FDA has on occasion placed the accessories in a different class (see, for example, 21 C.F.R § 876.5540, "Blood access device and accessories").

• ***Issuance of a unique, separate classification regulation or order[8] for the accessory***. In these cases, a classification regulation, separate from that of the parent device, has been established. Classification of accessories in this manner "has traditionally been considered for accessory types that may be used with multiple parent devices or that have unique standalone functions."[9]

In the Draft Accessory Guidance, FDA states it believes that the regulation of accessories should be risk-based and acknowledges that "the risk profile of an accessory can differ significantly from that of the parent device, warranting differences in regulatory classification."[10] FDA encourages manufacturers of new types[11] of accessories to pursue classification through the Automatic Evaluation of Class III Designation (*de novo* classification) process. The draft guidance provides additional information on the type of information that should be submitted to support a *de novo* petition for an accessory device.

The concepts outlined in the Draft Accessory Guidance may be most useful for companies planning to seek PMA approval for a device with which lower risk accessories may be used. It is worthwhile to consider whether seeking separate classification of those accessories, through the *de novo* process, would be beneficial for regulatory and/or business reasons, rather than simply treating the accessories as Class III devices.

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King & Spalding will continue to follow updates to FDA's proposal for the classification of medical device accessories. Please contact us if you would like to discuss any aspects of this draft guidance or if we can assist you in submitting comments.

[1] Draft Accessory Guidance available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf.
[2] Draft Accessory Guidance, p. 4.
[3] *Id.*
[4] *Id.*, p. 6.
[5] *Id.*
[6] *Id.*
[7] *Id.*, p. 2.
[8] Prior to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), reclassification of devices under Section 513(e) of the Federal Food Drug and Cosmetic Act was done through rulemaking: FDASIA changed this to an order process.
[9] Draft Accessory Guidance, p. 3.
[10] *Id.*, p. 6.
[11] Accessories that have already been classified (e.g., through the 510(k) or PMA process) are not eligible for *de novo* classification; however, manufacturers may seek reclassification of previously classified accessory devices through the reclassification process described in Section 513€ of the Federal Food, Drug, and Cosmetic Act.