Medical Device Accessories – Describing Accessories and Classification Mechanisms for Accessory Types

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Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Preface

Public Comment

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Medical Device Accessories – Describing Accessories and Classification Mechanisms for Accessory Types

Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

The Food and Drug Administration (FDA) developed this document to provide guidance to industry and FDA staff about the regulation of accessories to medical devices. This guidance is intended to describe FDA's policy concerning the classification of accessories and to discuss the application of that policy to devices that are commonly used as accessories to other medical devices. In addition, this document explains what devices FDA generally considers an "accessory" and provides guidance regarding various mechanisms that may be used to consider risk- and regulatory control-based classification of a specific accessory type.

The FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required. Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from the Center for Devices and Radiological Health (CDRH) or the Center for Biologics Evaluation and Research (CBER) involved in the review and decision-making aspects of the accessory classification process. "You" and "your" refer to the submitter of an accessory *de novo*, a reclassification petition for an accessory, and/or other related materials.

II. Background

FDA has jurisdiction over accessories because the definition of the term "device" provided in Section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) defines "device" to include, among other things, an "accessory."

> The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
> (2) 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
> (3) intended to affect the structure or 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 its primary intended purposes.

All accessories to products that meet the definition of "device" above are regulated under the FD&C Act. Accordingly, this guidance describes the types of devices that FDA generally considers as accessories and discusses the risk- and regulatory control-based classification paradigm for these accessories. This information is expected to provide a greater level of transparency with regards to the classification of accessories and will aid FDA staff and industry in assuring that these devices are subject to an appropriate level of regulatory oversight by FDA.

FDA has traditionally determined the classification of device accessory types in one of two ways:

- *First, by inclusion in the same classification as the parent device, which can be*:
    - *(1) Through operation of 510(k) Premarket Notification clearance.* In this case, the name of the classification regulation identifies only the parent device. However, FDA, through the 510(k) submission, may find accessories to the parent device to be substantially equivalent to either a predicate parent device with a similar intended use or a predicate accessory that has previously been cleared under the parent device's classification regulation. These accessories would thus be classified within the same classification as the parent device. Similarly, when the parent device classification regulation identifies only certain accessories, FDA may determine additional accessories to be classified under the regulation through the submission of a 510(k) by the sponsor demonstrating substantial equivalence of the parent device with new accessories to the parent device with the predicate accessories.

- *(2) Through operation of Premarket Application (PMA) approval.* Accessories to an approved Class III device may also be approved in a PMA, in which case they would remain in Class III along with the parent device; or

- *(3) By express inclusion in the classification regulation[1] or reclassification order[2] for the parent device.* In this case, the classification done under Section 513(d), Section 513(e), or Section 513(f)(3) classification regulation specifically identifies the parent device type and the corresponding accessories. These classification regulations or orders typically place accessories in the same risk-based classification (e.g., Class I, II, or III) as the parent device but sometimes classify accessories into a different risk-based classification.

- *Second, by issuance of a unique, separate classification regulation for the accessory*. In this case, FDA has determined that a classification regulation for an accessory should be separate from that of the corresponding parent device. This type of classification has traditionally been considered for accessory types that may be used with multiple parent devices or that have unique standalone functions. In accordance with this second way, FDA may consider issuing a separate classification regulation for a specific category of accessories that has been identified as having a different risk profile from that of the parent device and thus requires a different level of regulatory controls to provide reasonable assurance of safety and effectiveness of the accessories. In cases where the accessory type under consideration has previously been classified, and the intended use is unchanged from the previously classified accessory type, a reclassification order would create a new classification regulation in the CFR.

The classification of accessory devices, as for non-accessory devices, should reflect the risks of the device when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended with the parent device, meets the criteria for placement in the class of the parent device. However, some accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class. For example, an accessory to a Class III parent device may pose lower risk that could be mitigated through general controls or general and special controls and thus could be regulated as Class I or Class II.

FDA has developed this guidance to clarify how its risk- and regulatory control-based classification framework applies to accessory devices and to discuss the mechanisms by which FDA, manufacturers, or other parties may seek the risk- and regulatory control-based classification of accessory types. Specifically, this guidance encourages manufacturers and other parties to utilize the *de novo* classification process under Section 513(f)(2) of the FD&C Act to request risk-based classifications of accessories of a new type. This process provides a pathway to Class I or Class II classification for accessories for which general controls or general and special controls provide a

[1] See Section 513(d) of the FD&C Act.

[2] Two reclassification processes are described in Section 513 (e) and 513(f)(3) of the FD&C Act. Prior to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), FDA reclassified devices under Section 513(e) of the FD&C Act through rulemaking; FDASIA changed this to an order process.

reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. In addition, this guidance provides a discussion of a mechanism whereby an interested party may request risk-based classification of an accessory that was included under the approval of a PMA for the corresponding parent device. Finally, this document provides guidance for how interested parties may seek a reclassification of a previously classified accessory.

III. Scope

This guidance document clarifies what FDA generally considers an "accessory" and clarifies how FDA's risk-based framework for classification applies to accessories to other medical devices. In this guidance, we describe considerations for determining applicable risk to all products that meet the definition of an accessory.

In addition, this guidance describes mechanisms by which an interested party may seek the risk-based classification of either a new (not classified) accessory type or an existing (previously classified) accessory type. This guidance describes use of the *de novo* classification process to classify accessories of a new type under Section 513(f)(2) of the FD&C Act. Accessories within an accessory type that already has been classified by regulation or order are not appropriate for classification through the *de novo* process.[3] Manufacturers of such devices and other interested parties may seek reclassification via the procedures described in Section 513(e) and 513(f)(3) of the FD&C Act. This guidance also covers mechanisms by which an interested party may request that FDA consider the risk- and regulatory control-based classification of a device that was originally marketed as an accessory to a Class III parent device.

The general principles described in this guidance document for the risk- and regulatory control-based regulation of accessories apply to both the classification of accessories of a new type under Section 513(f)(2) and to reclassifications under Sections 513(e) and 513(f)(3).

FDA intends for the risk- and regulatory control-based classification paradigm discussed in this guidance to apply to all software products that meet the definition of an accessory.

Whether software that meets the definition of software as a medical device (SaMD) also meets the definition of accessory may be unclear. As part of the FDA's efforts for international convergence, the International Medical Device Regulators Forum (IMDRF) adopted the definition of SaMD as follows[4]:

"The term 'Software as a Medical Device' (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware

[3] Section 513(f)(2) was modified by Section 607 of Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), which created an alternative *de novo* pathway that does not require that the device be reviewed first under a 510(k) and be found not substantially equivalent (NSE) prior to submission of a *de novo*. Under the new *de novo* pathway, if a person believes their device is appropriate for classification into Class I or Class II and determines there is no legally marketed predicate device, they may submit a *de novo* without a precedeing 510(k) and NSE.

[4] See IMDRF SaMD WG/N10 Final: Software as a Medical Device (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf)

medical device.

NOTES:

- *SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.*
- *SaMD is capable of running on general purpose (non-medical purpose) computing platforms*
    - *"Computing platforms" include hardware and software resources (e.g. operating system, processing hardware, storage, software libraries, displays, input devices, programming languages etc.*
    - *"Operating systems" that SaMD require may be run on a server, a workstation, a mobile platform, or other general purpose hardware platform.*
- *'without being part of' means software not necessary for a hardware medical device to achieve its intended medical purpose;*
- *Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.*
- *SaMD may be used in combination (e.g., as a module) with other products including medical devices;*
- *SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software*
- *Mobile apps that meet the definition above are considered SaMD."*

SaMD meets the definition of "device" under the FD&C Act and is thus regulated by FDA. However, SaMD that uses data from a medical device does not automatically become an accessory for purposes of this guidance. For example, a software program that is intended to analyze radiological images or which analyzes specific data parameters generated by a device (e.g., blood pressure data, heart rate data) is considered a SaMD and would not be necessarily considered an accessory to the medical device. In other cases, software may meet the definition of SaMD and also "be interfaced with other medical devices." In that case, the software may be considered an "accessory" if it supports, supplements and/or augments the performance of a device, as described in Section IV below. Regardless of whether software meets the definition of a SaMD, the FDA intends to apply the same risk- and regulatory control-based classification paradigm discussed in this guidance.

IV. Definitions

A specific article may meet one or more of the definitions in this section depending on its stated intended use. For example, an article that meets the definition of an accessory may also be considered a component to a medical device if it is integral to the performance of a finished, packaged and labeled device. However, not all articles that meet the definition of a component will be considered an accessory. The policy described in this document is applicable only if we consider an article to be an accessory as described in this document.

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

Component (21 CFR 820.3(c)): "A raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of a finished, packaged, and labeled device."

Finished Device (21 CFR 820.3(l)): "Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized."

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

V. Accessory Classification

The policy governing the classification of accessories is subject to the same risk- and regulatory control-based scheme that FDA uses to classify all medical devices. The risks of an accessory are the risks that it presents when used with the corresponding parent device as intended. In order to classify an accessory, FDA addresses the following two questions:

1. Is the article an accessory?
2. What is the risk of the accessory when used as intended with the parent device(s) and what regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?

The answers to these two questions inform the risk- and regulatory control-based classification of a potential accessory pursuant to the criteria at Section 513(a)(1) of the FD&C Act. Individual accessories may either be classified pursuant to the same regulation of a corresponding parent device or be regulated independently. The following subsections provide further details and considerations regarding the risk-based classification for accessories.

A. Is the article an accessory?

The accessory classification process begins with the analysis of whether the article under consideration is an accessory as defined in this guidance document. We consider an accessory as an article that:

1. **<u>Is intended for use with one or more parent devices.</u>**

   FDA expects that whether an article is intended for use with a parent device will generally be determined by the labeling and promotional materials for the potential accessory device (rather than by the labeling and promotional materials for the parent device). If labeling, promotional materials, or other evidence of intended use demonstrate that an article is intended for use with a parent device (either a particular brand or a device type), and it supports, supplements or augments that device, FDA generally considers the article to be an accessory, and thus a "device" under section 201(h) of the FD&C Act.

It is important to note that FDA does not generally consider articles that do not meet the definition of an accessory as accessories simply because they may be used in conjunction with a device. For example, FDA would generally not consider a mobile phone that is used as a general platform for applications that include mobile medical applications that are medical devices, or an off-the-shelf computer monitor used to display medical data as accessories unless they are specifically intended for use with such medical devices.

2. **Is intended to support, supplement, and/or augment the performance of one or more parent devices.**

A device *supports* the performance of a parent device by enabling or facilitating that device to perform according to its intended use. For example, a rechargeable battery that is intended to operate when paired with an automated external defibrillator (AED) supports an AED by enabling it to defibrillate. In this case, the accessory is necessary to enable the parent device to meet its intended use. An infusion pump stand also supports the intended use of a parent device (an infusion pump) by holding medications or liquids and other infusion accessories firmly, at an appropriate height, and in convenient reach of the patient or caregiver. In this case, the parent device can perform its intended use without the accessory, but the accessory nonetheless supports the performance of the device.

A device *supplements* the performance of a parent device if it adds a new function or a new way of using the parent device, without changing the intended use of the parent device. For example, a pulse oximeter allows a multi-parameter monitor to display oxygen saturation but does not change its intended use, which is to record and display multiple physiological parameters. Similarly, a new balloon catheter used to insert an already approved transcatheter heart valve into a smaller diseased artery supplements the parent device's intended use. The balloon catheter supplements the intended use of the transcatheter heart valve by expanding the population of patients who can receive the parent device to those with smaller diameter arteries, such as women.

A device *augments* the performance of a parent device by enabling the device to perform its intended use more safely or effectively. *Augments* includes improving the performance of a parent device by enabling it to perform more quickly or improving usability or convenience for the device user. For example, a guidewire augments the performance of a bone-cutting instrument by increasing precision of the parent device and reducing the risk to the patient. Similarly, tools for the placement of an implantable nerve stimulator according to its intended use augment the performance of the stimulator by facilitating successful placement. Finally, a software program that adds color or contrast filters to enhance raw images generated by an imaging device augments the performance of a parent device by enabling to perform more effectively.

In practice, the distinctions among devices that support, supplement, or augment parent devices are subtle and many devices that meet the definition of an accessory may do more than one of these things. Thus, if the device is intended to support, supplement, *and/or* augment the performance of one or more parent devices, we intend to consider the device to be an accessory.

A product intended to be used with a medical device but which does not meet the definition of an accessory is not eligible for independent risk- and regulatory-control based classification separate from the corresponding parent device. For example, an optional case for a dental mouth guard would not generally be considered to meet the definition of an accessory and thus would not be eligible for classification separate from the parent device. Also, some products that are not specifically intended for use with a medical device and which do not meet the definition of an accessory may not warrant independent classification if they are not devices under Section 201(h) of the FD&C Act. As an example, non-device-specific off-the-shelf replacement parts (e.g., batteries, USB cables, computer mouse etc.) may be used with a medical device, but FDA does not intend to consider these products to be accessories or medical devices.

B. What are the risks of the accessory when used as intended with the parent device(s) and what regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?

Under the policy described in this guidance, FDA intends to determine the risk of accessories and the controls necessary to provide a reasonable assurance of their safety and effectiveness according to their intended use in the same manner that is used to determine such for devices that are not accessories. Because accessories are intended to be used with and to support, supplement, and/or augment one or more parent devices, FDA intends to determine the risks of accessories when used, as intended, with the parent device type.

Determining the risks of accessories according to their use with parent devices does not mean that all risks of a parent device are imputed to the accessory; the risk profile of an accessory can differ significantly from that of the parent device, warranting differences in regulatory classification. In determining the classification of an accessory, FDA intends to evaluate the risks imposed by the accessory's impact on the parent device and any unique risks of the accessory independent of its parent device. As with the classification of any other device, the types of regulatory controls necessary to control these risks of the use of the accessory device with the parent device will determine the regulatory class for accessories.

VI. Accessory Classification Mechanisms

The risk- and regulatory control-based classification for medical device accessories described in this guidance is applicable to both the classification of new accessory types and also for the potential reclassification of previously classified accessory types.

Accessories could fall into one of several classification categories, each of which may have a different process(es) for classification or reclassification:

- Accessories of a new type, which are not covered by any classification regulation and have no approved PMAs or cleared 510(k)s for devices of the same type;
- Accessories to a postamendments Class III device that were included under the PMA approval for the parent device system, but for which there is no classification regulation;
- Accessories to a postamendments Class III device that were the subject of a PMA approval but for which there is no classification regulation;
- Accessories that are covered by a classification regulation, including (1) accessories to a preamendments device type that has a Class III classification regulation and (2) accessories that fall under Class I or Class II classification regulations.

In the following sections, FDA describes the mechanisms by which each accessory category mentioned above may undergo risk- and regulatory-control-based classification. Prior to submitting request for classification or reclassification of an accessory type, FDA strongly recommends that a that a sponsor submit a Pre-Submission in order to solicit input regarding the appropriate classification categorization (see bullets above) of the accessory under consideration and the processes available to pursue classification. In the context of a Pre-Submission, we recommend that a sponsor include a discussion of how the proposed accessory fits into one of the classification categories identified above and a proposed classification for the accessory with an explanation of how the accessory has a risk profile that is different from that of the parent device.

A sponsor also may submit a 513(g) Request for Information[5] to obtain information about device classification and regulatory requirements applicable to a type of device. Additional information regarding 513(g) Requests is available in FDA's guidance entitled "FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Dug, and Cosmetic Act" (the 513(g) guidance). We recommend that the 513(g) Request include the information provided in Appendix 1 below, as applicable, in addition to the information recommended to be submitted as outlined in the 513(g) guidance. It should be noted that FDA's response to a 513(g) Request for Information is based on the information provided in the request and is not a classification decision for a device, does not constitute FDA clearance or approval, and does not mean that FDA has determined that the device complies with any requirements of the FD&C Act or any other federal laws or regulations.

A. Classification of New Accessory Types through the *De Novo* Process

[5] *See* Section 513(g) of the FD&C Act (21 U.S.C. 360c(g)).

FDA encourages manufacturers and other parties (hereafter "submitter") to utilize the *de novo* classification process in Section 513(f)(2) of the FD&C Act to request risk-based classifications of new types of accessories. In order to be considered a new accessory type, the accessory under consideration should not be covered by an existing classification regulation and there should not be any approved PMAs or cleared 510(k)s for that accessory type. This *de novo* classificaiton process provides a pathway to Class I or Class II classification for accessories with low to moderate risk for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there are no legally marketed predicate devices.

In accordance with Section 513(f)(2), a submitter may submit a *de novo* requesting FDA to make a classification determination for the accessory according to the criteria in Section 513(a)(1) of the FD&C Act. The *de novo* must include a description of the device and detailed information and reasons for the recommended classification (see section 513(f)(2)(A)(v) of the FD&C Act[6]). Please refer to Appendix 1 for the information FDA recommends be submitted in a *de novo* request for a new type of accessory.

FDA must make a classification determination for the device that is the subject of the *de novo* by written order within 120 days of the request (see Section 513(f)(2)(A)(iii) of the FD&C Act).

If the submitter demonstrates that the criteria in Section 513(a)(1)(A) or (B) of the FD&C Act are met (i.e., accessories for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness), FDA will grant the *de novo*, which classifies the new accessory (and accessory type) in Class I or Class II. The accessory may then be marketed immediately and serve as a predicate device for future 510(k) premarket notifications, if applicable. FDA will publish a notice in the Federal Register announcing the classification and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness of the accessory. If the *de novo* is declined[7], the accessory remains in Class III under Section 513(f)(1) of the FD&C Act and may not be marketed until a PMA is submitted by the sponsor and approved by FDA.

B. Classification of Accessories Approved Under PMAs For Postamendments Class III Parent Devices

Under Section 513(f)(1) of the FD&C Act, postamendments devices that FDA has not previously classified based on the criteria at Section 513(a)(1) of the FD&C Act are

[6] See also Section 513(f)(2)(A)(v) of the FD&C Act, which states: "The person submitting the request for classification…may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification."

[7] A *de novo* could be declined for reasons including if the performance data provided in the *de novo* request do not support that general controls or general and special controls can appropriately mitigate identified risks to health for the device to provide a reasonable assurance of safety and effectiveness.

"automatically" or "statutorily" classified into Class III, regardless of the level of risk they pose or the ability of general controls or general and special controls to provide a reasonable assurance of safety and effectiveness.

An accessory (or multiple accessories) to a Class III parent device may be marketed via approval of a post-amendments Class III parent device system that includes these accessories. An interested party may request that FDA consider the risk-and regulatory-control-based classification of a device that was originally marketed as an accessory to a Class III parent device. These requests can be submitted via several mechanisms depending on whether or not the accessory under consideration has previously been classified on the basis of risk and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. The options available for interested parties to seek a risk-and regulatory control based classification of a product that was originally approved as an accessory to a Class III parent device are as follows:

1. **510(k) Premarket Notification Process:** In some cases, an accessory that was marketed as part of a parent device system may, when used independently of that system, be considered to be substantially equivalent to an accessory type that has been previously classified in Class I or Class II. For example, a facemask that was originally approved as a patient interface accessory to a Class III drug delivery system may be "pulled out" from the parent device system and seek separate classification in either Class I or Class II. An interested party may submit a 510(k) Premarket Notification to demonstrate that an accessory that was originally marketed with a Class III parent device is substantially equivalent to a previously cleared product (predicate device) that falls within an accessory type classified into Class I or II. If FDA clears the 510(k) Premarket Notification, the accessory will then be classified in the same classification as the cited predicate device. During the review of a 510(k), FDA may determine that the risk profile of the accessory is different (higher) than that of the referenced predicate device and that general and specific regulatory controls are not sufficient to assure a reasonable assurance of safety and effectiveness. In this case, the 510(k) would be determined to be "not substantially equivalent" and the accessory would not warrant classification separate from that of the corresponding parent device.

2. **De Novo Process:** If the accessory type under consideration has not been previously classified, it may be eligible for risk-based classification in accordance with the *de novo* process (as described above in Section A). In order to warrant the separate classification of an accessory from that of an associated Class III parent device, the accessory should have a different (lower) risk profile than that of the parent device. If FDA deems that an accessory may be appropriately classified separately from a Class III parent device on the basis of risk, the accessory may be considered for classification via the *de novo* process.

3. **513(f)(3) Reclassification Process:** An interested party that believes that it is appropriate for FDA to consider a separate classification of the marketed accessory on the basis of risk and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory may seek

reclassification of that accessory. In this case, FDA would consider whether or not the accessory under consideration can be "pulled out" from the parent device approval and be classified separately on the basis of applicable risk and regulatory controls.

Section 513(f)(3) of the FD&C Act applies specifically to the reclassification of postamendments devices that are Class III in accordance with Section 513(f)(1). Reclassification of accessories under this section may be initiated either by the FDA or by a petition from the manufacturer or importer of the device.[8] In order to change the classification of the device, it is necessary that the proposed class have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use. FDA may seek input from a device classification panel, if appropriate, regarding a reclassification effort. Once all information has been considered, the FDA will issue an order approving or denying the petition. If the FDA approves the petition, the order will describe the reasons for reclassification and identify the risks to health (if any) presented by the device type.

C. Reclassification of Accessories That Were the Subject of a PMA Approval

Accessories to a postamendments Class III device that were the subject of a PMA approval are eligible for reclassification via the 513(f)(3) Reclassification Process. In this case, FDA evaluated the risks associated with the accessory and has determined that general controls or general and special controls are insufficient to provide a reasonable assurance of safety and effectiveness. Accordingly, the accessory has been classified in Class III. In order for an accessory in this category to be classified into either Class I or Class II, the 513(f)(3) Reclassification Process should establish that the proposed classification for the accessory has sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

D. Classification of Accessories That Are Covered By A Classification Regulation

Accessories that were previously classified by regulation include (1) accessories of a preamendments type identified in a Class III classification regulation; and (2) accessories that fall under Class I or II classification regulations (e.g., (1) if they are identified in the classification regulation, (2) if the accessory would fall under such a regulation by virtue of 510(k) clearance to a predicate under such the classification regulation, or, (3) if 510(k) exempt, by virtue of FDA's acknowledgement that an accessory falls within such regulation). Accessories to a preamendments parent device may be identified in the Class III classification regulation as a group (e.g., Product X and Accessories) or individually (e.g., Product X and Accessories A, B and C). Please note that in some cases, the existing classification regulation may be specifically for an accessory (not for a parent device that

[8] Under 21 CFR 860.134 a manufacturer of a device filing a petition for reclassification of the device or accessory must be in accordance with 21 CFR 860.123.

includes that accessory). For accessories that are covered by a classification regulation, the mechanisms available for risk- and regulatory-control based classification are as follows:

1. **510(k) Premarket Notification Process:** An accessory that is determined to be substantially equivalent to an accessory of the same type that falls under a Class I or Class II classification regulation will be cleared under that classification regulation.

2. **513(e) Reclassification Process:** An accessory that is identified in a preamendments Class III classification regulation is considered classified. Under Section 513(e) of the FD&C Act, the FDA may, on its own initiative or in response to a petition from an interested person, reclassify a classified device type based on "new information." Section 513(e) is applicable to the reclassification of both a pre-amendments device types (a device that was available on the market before the enactment of the Medical Device Amendments to the FD&C Act, on May 28, 1976) and a post-amendments device type (a device that was not available on the market before the enactment of the Medical Device Amendments to the FD&C Act, on May 28, 1976) that has been classified or reclassified into Class I or Class II. If the FDA or a petitioner proposes that the device type be reclassified into a lower class (from Class III to Class II, Class II to Class I, or Class III to Class I), the FDA or the petitioner must identify new information to support a determination by the FDA that the safety and effectiveness of that device type can be assured through the establishment of the appropriate regulatory controls (general and/or general and special controls) for classification into a lower class. This type of reclassification requires (1) an administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, (2) a meeting of a device classification panel, and (3) consideration of comments to a public docket.

A product that is currently marketed as an accessory to a preamendments Class III parent device may warrant risk- and regulatory-control based classification via the *de novo* process if it is not identified in the classification regulation for the preamendments Class III device. Accessories that are identified in the classification regulation for a preamendments Class III parent device are considered classified and are thus not eligible for the *de novo* process.

Appendix 1 – Request for Accessory *De Novo* Classification

Manufacturers or other interested parties may seek a decision by the FDA on the appropriate risk-based classification of a new type of accessory by filing a *de novo* request (hereafter a "*de novo*") under section 513(f)(2) of the FD&C Act. This process is also known as the *de novo* classification process.[9]

[9] See "New Section 518(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff," February 19, 1998, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance

In order to streamline the submission and evaluation of the accessory *de novo* so that only information necessary to assess accessory safety and effectiveness is submitted and reviewed, we recommend that the following information be provided:

- Clear identification as a *de novo* request for a new accessory device type;
- Device Information and Summary:
  - A description of the relevant parent device(s);
  - A description of the ability for the accessory to be compatible with a specific parent device, multiple parent devices, or a class of devices;
  - A description of the technical characteristics of the accessory, which ensure compatibility with a specific parent device, multiple parent devices, or a class of devices;
  - A description of how the accessory supports, supplements and/or augments the performance of the parent device.
- Identification of parent products(s) to which the accessory is compatible, including model number, connector type, etc.;
- Classification summary and recommendation:
  - The classification summary should include a rationale for why the accessory device does not fit within any identified classification for the parent device(s);
- An identification of the risks to health presented by the accessory device and proposed mitigation measures;
- Proposed controls:
  - For proposed class II devices, a list of general and special controls that sufficiently mitigate the risks to health, including compatibility of the accessory device with parent device and a description of how the proposed special controls will provide a reasonable assurance of safety and effectiveness for the accessory device
  - For proposed class I devices, an identification of how the application of general controls only would sufficiently mitigate the risks to health and would provide a reasonable assurance of safety and effectiveness of the accessory device;
- Summary of the performance data supporting the *de novo*:
  - Reference to all reasonably known relevant data and information, including new information, about the accessory device and/or in combination with the parent device(s), whether favorable or unfavorable to the proposed classification; and
- Labeling of the accessory with adequate instructions for use with the parent device(s):
  - Include labeling instructions to address compatibility of the new accessory device and the parent device(s), including any relevant performance data to support compatibility; and
  - Include relevant technical characteristics of the accessory.

Documents/ucm080195.htm. On August 14, 2014, FDA proposed new thinking on *de novo* classification in its draft guidance entitled "*De Novo* Classification Process (Evaluation of Automatic Class III Designation)," available at http://www.fda.gov/downloads/ Medical Devices/DeviceRegulationandGuidance/ GuidanceDocuments/ UCM273903.pdf.

In preparing a *de novo* request for a new accessory device, we suggest you review publicly posted information, including decision summary documents, for recently granted CDRH *de novos* available on our website at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm.

In an effort to further streamline and facilitate FDA's review of your accessory *de novo* classification request, we recommend that you provide a draft executive summary document with the following information:

- Administrative information,
- Proposed identification language for a new classification regulation or order;
- Summary of the accessory device, including a detailed description of the accessory, including any necessary technical characteristics and compatibility information with the parent device(s);
- Summary of the performance data to support the proposed classification recommendation;
- Risk and Mitigation Information: for class I accessory devices, an explanation of how general controls adequately mitigate any risks to health; for class II accessory devices, listing of the risks and mitigation measures, including the special controls necessary to mitigate the risks to health; and
- Benefit/Risk Considerations.[10]

You may also consider the applicability for future 510(k) submissions under a separate process authorized by section 510(m)(2) to seek exemption from the requirements of section 510(k).

[10] For information on benefit-risk determinations and factors considered, please see FDA guidance entitled "*Guidance for Industry and Food and Drug Administration Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications," available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm267829.htm.