Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types

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

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Preface

Public Comment

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

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 guidance explains what devices FDA generally considers an "accessory" and encourages use of the *de novo* classification process under Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow manufacturers and other parties to request risk- and regulatory control-based classification of accessories of a new type (i.e., accessories of a type that has not been previously classified under the FD&C Act, cleared for marketing under a 510(k) submission, or approved in an application for premarket approval (PMA)).

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 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 articles 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 the same intended use and technological characteristics, or different technological characteristics that do not raise different questions of safety and effectiveness, or a predicate accessory that has previously been cleared under the parent device's classification regulation with the same intended use and technological characteristics, or different technological characteristics that do not raise different questions of safety and effectiveness. 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 title of the classification regulation specifically cites the name of the parent device type and the corresponding accessories. These classification regulations or orders typically place accessories in the same risk- and regulatory control-based classification (e.g., Class I, II, or III) as the parent device but sometimes classify accessories into a different risk- and regulatory control-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.

On December 13, 2016, section 513(b) of the FD&C Act was amended by the 21st Century Cures Act (Public Law 114-255) to state that the "Secretary shall classify an accessory . . . based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used." Accordingly, 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

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

[2] Two reclassification processes are described in Section 513 (e) and 513(f)(3) of the FD&C Act, 21 U.S.C. 360c(e) and (f)(3). 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 (21 U.S.C. 360c(e)) through rulemaking; FDASIA changed this to an order process.

Class I or Class II.

FDA has developed this guidance to describe how the FD&C Act's risk- and regulatory control-based classification framework applies to accessory devices and to encourage manufacturers and other parties to utilize the *de novo* classification process under Section 513(f)(2) of the FD&C Act to request risk- and regulatory control-based classifications of accessories of a new type that are low to moderate risk and for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

III. Scope

This guidance document describes what FDA generally considers an "accessory" and how the FD&C Act's risk- and regulatory control-based framework for classification applies to accessories to other medical devices. In this guidance, we describe considerations for determining applicable risk to all articles that meet the definition of an accessory. This guidance is only applicable to articles that meet the definition of a device under section 201(h) of the FD&C Act.

In addition, 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, or has received PMA approval, are not appropriate for classification through the *de novo* process.[3] Manufacturers of such devices and other interested parties may seek reclassification[4] or exemption from the requirement to submit a 510(k) notification[5] under applicable sections of the FD&C Act.

While the general principles and mechanisms described in this guidance document for the risk- and regulatory control-based regulation of accessories apply to reclassifications for existing accessories under Sections 513(e) and 513(f)(3), this guidance focuses on the application of these principles in the de novo classification process for the classification of accessories of a new type under Section 513(f)(2).

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, including those that may also meet the definition of "Software as a Medical Device (SaMD)."

As part of the FDA's efforts for international convergence, the International Medical Device Regulators Forum (IMDRF) adopted the definition of SaMD as "software intended to be used for

[3] Section 513(f)(2) of the Act, 21 U.S.C. 360c(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 preceding 510(k) and NSE.

[4] *See* Sections 513(e) and 513(f)(3) of the FD&C Act.

[5] *See* Section 510(m) of the FD&C Act.

one or more medical purposes that perform these purposes without being part of a hardware medical device."[6]

SaMD that meets the definition of a device under the FD&C Act is regulated by FDA. However, SaMD that meets this device definition and uses data from a medical device does not automatically become an accessory for purposes of this guidance. For example, a stand-alone software program that is intended to analyze radiological images or analyzes specific data parameters generated by a device (e.g., blood pressure data or heart rate data) is considered a SaMD but would not be considered to support, supplement, and/or augment the performance of the device that generated data, and therefore, would not be an accessory.

In some cases, software that meets the definition of SaMD may be used in combination (e.g., as a module) with other devices. In these cases, the SaMD may also be considered an accessory if it supports, supplements, and/or augments the performance of one or more parent devices, as described in Section IV below.

Regardless of whether a SaMD uses data from other devices or is used in combination with other devices, the FDA intends to apply the same risk- and regulatory control-based classification paradigm discussed in this guidance to all software products that meet the definition of SaMD and also meet the definition of an accessory.

IV. Definitions

Accessory: A finished 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]ny raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device."

Finished Device (21 CFR 820.3(l)): "[A]ny device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized."[7]

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

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[6] *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)

[7] Note that the preamble to the Quality System Final Rule (61 FR 52609, October 7, 1996) states "To better clarify its intent, FDA has amended the definition to add that all devices that are capable of functioning, including those devices that could be used even though they are not yet in their final form, are 'finished devices.' For example, devices that have been manufactured or assembled, and need only to be sterilized, polished, inspected and tested, or packaged or labeled by a purchaser/manufacturer are clearly not components, but are now in a condition in which they could be used, therefore meeting the definition of 'finished device.'"

V. Accessory Classification Policy

The policy governing the classification of accessories is subject to the same risk- and regulatory control-based scheme under the FD&C Act 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 as a corresponding parent device or be regulated independently. The following subsections provide further details and considerations regarding the risk- and regulatory control-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 described in this guidance document. We consider an accessory as an article that:

1. Is intended for use with one or more parent devices.

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, and/or augments that device, FDA generally considers the article to be an accessory and, thus, a "device" as defined in 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 tunneling tool for a neurostimulation device that is intended to create a conduit for the leads between the target location to the neurostimulator supports the neurostimulator by facilitating it to provide stimulation to the target neural tissue. 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, 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 it 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.

Some products that are not specifically intended for use, but nevertheless may be used, 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 regulatory 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.

C. Classification of New Accessory Types through the De Novo Process

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- and regulatory control-based classifications of new types of accessories. In order to be considered a new accessory type, the accessory under consideration should not be classified by an existing classification regulation and should not be the subject of any approved PMAs or cleared 510(k)s for that accessory type. This *de novo* classification 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* request 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* request 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[8]). 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* request 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* request, 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 request to undertake *de novo* classification is declined,[9] 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.

VI. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 180 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate to:

[8] *See* also Section 513(f)(2)(A)(v) of the FD&C Act, 21 U.S.C. 360c(f)(2)(A)(v), 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."

[9] A request to undertake the *de novo* classification 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.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0823 (expires 09-30-2019).

Appendix 1 – Request for Accessory *De Novo* Classification

Manufacturers or other interested parties may seek a decision by the FDA on the appropriate risk- and regulatory control-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.[10]

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 product(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 the 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 the accessory in

[10] *See* "New Section 513(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 Documents/ucm080195.htm.

combination with the parent device(s), whether favorable or unfavorable to the proposed classification; and

- Labeling for 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.

In preparing a *de novo* request for an accessory of a new type, 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.[11]

[11] For information on benefit-risk determinations and factors considered, please see FDA guidance titled "*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.