U.S. FOOD & DRUG ADMINISTRATION

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

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Agenda

- Key Take-Aways
- Overview of the Accessories Guidance
  - Background and Scope
  - Classification of Accessories
  - Key Definitions
  - Applying the Accessories Policy
- Q & A

Key Take-Aways

- The FDA is taking a risk-based approach to classifying accessories when used as intended with a parent device
  - New types of accessories can be a lower classification than the parent device
  - The FDA encourages manufacturers to use the *de novo* process to request risk-based classification of new types of accessories
- The final Accessories Guidance provides clarification on the definition of a medical device accessory

Accessories Guidance Background

- Draft Guidance on Medical Device Accessories published January 20, 2015
- We received 10 sets of comments
- No significant policy changes resulted from the comment period
- Final guidance published December 30, 2016

Scope of Guidance

- Only applicable to devices under section 201(h) of the Food, Drug, and Cosmetic Act (FD&C Act)
  - Scope of "Software as a Medical Device" (SaMD) is limited to those that meet the definition of a device under the FD&C Act

- Focuses on the use of the *de novo* classification process to classify accessories of a new type

What about existing accessories?

- Reclassification under 513(e) and 513(f)(3) of the FD&C Act for existing accessories
  - Principles in guidance apply to existing accessories
- Through Medical Device User Fee Amendments IV (MDUFA IV) user fee negotiations, the FDA and industry have committed to working together to identify the appropriate reclassification pathway for existing Class III accessories

Historical Regulation of Accessories

- Inclusion in the same classification as the parent device
  - Through 510(k) Premarket Notification clearance
    - substantial equivalence to another accessory or to another 510(k) cleared device
  - Premarket Application (PMA) approval
  - Explicit inclusion in classification regulation or reclassification order for the parent device.
- Issuance of a unique, separate classification regulation for the accessory

Approach Moving Forward: Risk-Based Classification of Accessories

- On December 13, 2016, section 513(b) of the FD&C Act was amended by the 21st Century Cures Act 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."

Risk-Based Classification of Accessories

- Classification of accessories should reflect the risks of the accessory device when used as intended
  - Some accessories can have a lower risk profile than the parent device & be regulated in a lower class
  - Some accessories can have the same risk profile as the parent device & be regulated in the same class

Definitions

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

- **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."

Definitions

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

Applying the Accessory Classification Policy

1. Is the device an accessory?
   a. Is it intended for use with one or more parent devices?
   b. Is it intended to support, supplement, and/or augment the performance of one or more parent devices?
2. 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?

1. Is the device an accessory?

a. Is the device intended for use with one or more parent devices?
   - Determined by the labeling for the potential accessory device (not of the parent device)
   - Articles used with a device that are not finished devices are not accessories e.g.,:
     - Off-the-shelf computer monitor and peripherals

1. Is the device an accessory?

b. Is the device intended to support, supplement, and/or augment the performance of one or more parent devices?
   - Does it *support* the performance of a parent device by enabling or facilitating that device to perform according to its intended use? e.g.,:
     - Tunneling tool for use with a neurostimulator to enable proper lead placement
     - Infusion pump stand

1. Is the device an accessory?

b. Is it intended to support, supplement, and/or augment the performance of one or more parent devices?
   - Does it *supplement* the performance of a parent device by adding a new function/new way of using the parent device without changing the intended use of the parent device? e.g.,:
     - New delivery system that expands the patient population in which the parent device can be used
     - Input device (e.g., thermometer) to a multi-parameter monitor

1. Is the device an accessory?

b. Is it intended to support, supplement, and/or augment the performance of one or more parent devices?
   - Does it *augment* the performance of a parent device by enabling the device to perform its intended use more safely or effectively? e.g.,:
     - Bone cutting guides used to assist in the positioning of total hip or knee arthroplasty components
     - Color/contrast filters to enhance raw images generated from the parent imaging device

Software as a Medical Device (SaMD)

- SaMD – software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. *See the* International Medical Device Regulators Forum (IMDRF) SaMD WG/N10 Final Document: Software as a Medical Device (http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf)

- SaMD that meet the definition of a device under the FD&C Act
  - similar to other stand-alone devices SaMD are classified according to their risk

Software as a Medical Device (SaMD)

- SaMD using data from another device
  - does not automatically become an accessory,
  - is not considered to support, supplement, and/or augment the performance of a parent device
  - For example, a stand-alone software program that is intended to analyze radiological images is not considered an accessory
- SaMD is considered an accessory
  - when SaMD is used in combination (e.g., as a module) with other devices and supports, supplements, and/or augments the performance of these other parent devices

Accessory Determination Example

- A stand-alone pulse oximeter
  - Not intended to be used with a parent device
  - Not intended to support, supplement or augment a parent device
  - ➢ Not an accessory
- A pulse oximeter intended to be used with a multi-parameter monitor
  - Intended to be used with a parent device (multi-parameter monitor)
  - Intended to supplement the multi-parameter monitor to display oxygen saturation but does not change its intended use
  - ➢ The pulse oximeter is an accessory to the multi-parameter monitor

2. Risk of accessory and necessary regulatory controls?

a. Is it a new type of accessory? Yes if:
   - Not classified by an existing classification regulation
   - Not cleared in a 510(k)
   - Not approved in a PMA
   - ➢ New intended use for an already cleared/approved accessory may be considered a new type of accessory

If it is not a new type of accessory, current options are to request reclassification under 513(e) or 513(f)(3)

2. Risk of accessory and necessary regulatory controls?

If it is a new type of accessory, assess eligibility for class I or II classification via *de novo* request:

a. Does the accessory pose low-moderate risk?
b. Can general controls or general and special controls provide a reasonable assurance of safety and effectiveness?

Key Take-Aways

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Additional Information

- Information on device determination:

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm

- Unsure if your device is a new type of accessory?
  - Contact the relevant review division
- Inquiries about SaMD

  -- digitalhealth@fda.hhs.gov
- General Inquiries
  - Division of Industry and Consumer Education: DICE@fda.hhs.gov

Panel Discussion

- Angela Krueger, Deputy Director, Office of Device Evaluation (Acting)
- Scott McFarland, Associate Director, Office of In Vitro Diagnostics and Radiological Health
- Bakul Patel, Associate Director for Digital Health
- Jonette Foy, Associate Director for Policy (Acting)
- Erica Takai, Assistant Director for Guidance Management

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Questions?

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Under Heading 'How to Study and Market Your Device Classification'