ODE Updates

OSMA Fall Meeting

April 19, 2018

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Center for Devices and Radiological Health
Food and Drug Administration

Outline

- Current ODE Structure
- Guidance Updates
- FDA Reauthorization Act of 2017 (FDARA)

CURRENT ODE STRUCTURE

Current ODE Structure

Name	ODE Role
William Maisel, MD, MPH	Director
Angela Krueger *(acting)*	Deputy Director, Engineering & Science Review
Barbara Zimmerman	Deputy Director, Premarket Program Management
Randall Brockman, MD	Deputy Director, Clinical
Aron Yustein *(acting)*	Chief Medical Officer
Rebecca Nipper *(acting)*	Associate Director, Guidance & Regulation
Owen Faris, PhD	Clinical Trials Director

Other Groups in ODE

Name	ODE Role
Sharyn (Lesa) Dowtin	Director, Program Management Office
Joshua Nipper	Chief, Premarket Approval (PMA) Staff
Soma Kalb	Chief, Investigational Device Exemption (IDE) Staff
Marjorie Shulman	Chief, Premarket Notification (510(k)) Staff
Sergio de del Castillo *(acting)*	De Novo Program Lead
James Swink	Advisory Panel Coordinator

GUIDANCE UPDATES

Guidance Updates

- Overview of Significant Guidances
  - 510(k) Modifications Guidances (General & Software)
  - Least Burdensome Guidance
  - Accessories Guidance
- FY18 Guidance Priorities

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510(k) Modifications Guidances: General & Software

Published on October 25, 2017

FDA Guidance Goals

- FDA made targeted changes to original *Deciding When to Submit* guidance from 1997:
  - Clarity, including interpretation of key regulation terms such as “could significantly affect”
  - Flowcharts – matched with text
  - Key principles
  - Materials changes
  - Examples to illustrate use of guidances
  - Documentation recommendations and examples
- Separate software guidance based on same key principles
- Addition of risk assessment paradigm

Guidance Scope

- Both guidances apply to legally marketed devices subject to 510(k) requirements
  - Excludes PMA devices and 510(k)-exempt devices
- General Guidance and Software:
  - General guidance **does not** apply to software-specific changes.
  - General guidance **does** apply to non-software changes to software devices or devices containing software (e.g., labeling).
  - When multiple changes affect labeling/hardware in addition to software, assess the changes using both guidances.
  - If use of either guidance leads to a "New 510(k)" conclusion, submission of a new 510(k) is likely required.
  - Guiding Principles are aligned between the guidances.

Guidance Structure

- Guiding Principles
- Logic scheme
  - Labeling changes (Section A)
  - Technology, engineering, and performance changes (Section B)
  - Materials changes (Section C)
  - IVDs (Section D)
  - Considerations for risk-based assessments of modified devices (Section E)
- Examples

How to Use The Guidances

- Guidances describes a logic scheme for determining when a 510(k) is required
- Include flowcharts for ease of use, but flowcharts are not intended to be used stand-alone
- In cases with multiple changes, manufacturers should use all applicable flowcharts and companion text
- Changes not addressed in Sections A through D should be evaluated with a risk-based assessment using the recommendations provided in Section E.

Reminder: Flowcharts are provided as a visual aid, but do not capture all necessary considerations. Refer to accompanying text when using flowcharts.

Software Modifications

- Same General Principles as with the General Guidance
- Software-specific policy
  - 4 Questions
    - Strengthen cybersecurity?
    - Return the system into specification of most recently cleared device?
    - Impacts of changes to risks/risk controls?
    - Significantly affect clinical functionality/performance specs?
  - Additional considerations
- Software-specific examples in Appendix of Software Modifications Guidance only

Additional Info

- General Modifications Guidance:

  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf

- Software Modifications Guidance:

  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737.pdf

- Webinar held November 16, 2017

  https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm581811.htm

Least Burdensome Guidance

- The Least Burdensome Provisions: Concept and Principles (Draft)
  - Published December 15, 2017
  - Comment period closed March 15, 2018

LB Principles

- LB principles should be interpreted broadly and applied across the total product lifecycle.
- CDRH has applied the LB approach and its goals in policies and programs, including:
  - Benefit-Risk Framework
  - Expedited Access Program (now Breakthrough Devices)
  - Utilization of RWE
  - Enforcement discretion policies (MMA, MDDS, General Wellness)
  - PMA retrospective review for reclassification, reduced premarket data collection, or pre/postmarket shift
  - Cures Act Class I and Class II exemptions

Least Burdensome Definition

The minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time.

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Guiding principles

- FDA intends to request the minimum information necessary to adequately address the regulatory question or issue at hand.
- Industry should submit material, including premarket submissions, to FDA that are least burdensome for FDA to review within applicable regulatory requirements.
  - Industry should submit well-organized, clear, and concise information.

Guiding principles

- FDA intends to use the most efficient means to resolve regulatory questions and issues.
- The right information should be provided at the right time (e.g., just-in-time data collection) to address the right questions.
- Regulatory approaches should be designed to fit the technology, taking into account its unique innovation cycles, evidence generation needs, and timely patient access.
- FDA intends to leverage data from other countries and decisions by or on behalf of other national medical device regulatory authorities to the extent appropriate and feasible.
- FDA intends to apply least burdensome principles in international medical device convergence and harmonization efforts.

Additional Info

- Least Burdensome Concepts and Principles (Draft):

  https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf

  (Comment period closed March 15, 2018)

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Accessories Guidance

Published on December 20, 2017

Key Take-Aways

- 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
- Provides clarification on the definition of a medical device accessory
- Outlines pathways for classification of accessories (Section 513(f)(6) of the FD&C Act)

Historical Classification of Accessories

- Inclusion in the same classification as the parent device
  - Through 510(k) Premarket Notification clearance
  - 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

What's New

- 21st Century Cures and FDARA amended the FD&C Act to change the authority and methods by which CDRH classifies medical device accessories:

  "…classify an accessory… based on the risks of the accessory when used as intended and level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used."

Accessory Classification Processes

- New Accessories:
  - Request for classification of an accessory type that has not been previously classified under the FD&C Act, cleared under a 510(k), or approved in a PMA
  - Bundled with PMA or 510(k)
  - Timeline for decision (grant or deny) aligns with PMA or 510(k) decision timeline

Accessory Classification Processes

- Existing Accessories:
  - Request for classification of an accessory type that has been previously classified under the FD&C Act, cleared under a 510(k), or approved in a PMA
  - Standalone request made by a manufacturer or importer who has been granted marketing authorization for that accessory
  - Manufacturer may request a meeting prior to submitting request utilizing pre-sub process
  - Decision (grant or deny) issued within 85 days

Accessory Decisions

- If granted, written order classifies accessory into class I or class II (special controls)
  - Federal Register Notice published announcing classification
- If denied, letter sent to manufacturer including a detailed description and justification for accessory classification determination.

Other Classification Options

- De Novo Request – for new accessories
- Reclassification under sections 513(e) and 513(f)(3) of the FD&C Act – for existing accessories

Additional Info

- Accessories Guidance:

  https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf

- Webinar *(does not discuss new FDARA provisions)*

  https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm534952.htm

FY18 Guidance Development

- **Final Guidance Topics (A-List)**
- Medical Device Accessories: Describing Accessories and Classification Pathway for New Accessory Types (revision) 
- Unique Device Identification: Policy Regarding Compliance Dates of Class I and Unclassified Devices 
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
- Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases 
- Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics 

FY18 Guidance Development

- **Draft Guidance Topics (A-List)**
- Export Certificates
- Multifunctional Device Products: Policy and Considerations
- The Least Burdensome Provisions: Concept and Principles
- Humanitarian Devices Exemption (HDE) Program
- 510(k) Third Party Review Program
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program
- Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria
- The Application of Acceptable Unce… to Support Marketing Authorization Decisions for Medica…
- Principles and Procedures for the R… Voluntary Consensus Standards
- Validation of Automated Process Equipment Software

Published 4/12/18
Comment period open through 7/11/18

FY18 Guidance Development

- **Final Guidance Topics (B-List)**
- Human Factors List of High Priority Devices
- Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics
- Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product
- **Draft Guidance Topics (B-List)**
- Premarket Submissions for Patient Matched Guides to Orthopedic Implants
- Replacement Reagents Policy for Technologically Similar Instruments for In Vitro Diagnostic Devices

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FDA REAUTHORIZATION ACT OF 2017 (FDARA)

Overview of FDARA

- Reauthorizes user fee collections for
  - Medical Devices (MDUFA)
  - Prescription Drugs (PDUFA)
  - Generic Drugs (GDUFA)
  - Biosimilars (BsUFA)
- Includes additional medical devices provisions related to
  - pediatric devices
  - inspections processes
  - the export certificate process
  - the regulation of contrast imaging agents
  - classification of accessories
  - evaluating the use of real world evidence in the postmarket context
  - over the counter hearing aids
  - third party servicing of medical devices

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Pediatric Devices

- FDARA sec. 502
- Requires additional information in CDRH's annual pediatric report to Congress, including:
  - An assessment of pediatric device labeling needs based on a review of real world evidence on the off-label use of medical devices in children; and
  - The number of devices for which extrapolation was used to support approval of pediatric labeling
- Allows emergency use of an HDE device if permitted by either an institutional review board or an "appropriate local committee"
- Allows pediatric device consortia (PDC) grant money to be spent on regulatory consultation activities
- Requires a public meeting about the development, approval/clearance, and labeling of pediatric medical devices to be held within 1 year of enactment (by 8/18/18)

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Pediatric Medical Device Development Public Meeting

August 13-14, 2018

FDA Main Campus

Silver Spring, MD

For information and registration:
https://go.usa.gov/xQbbM

Accessories

- FDARA sec. 707
- Decouples accessory classification from classification of the parent device
- Requires FDA to respond to accessory classification requests within 85 days for accessories previously classified
- Allows FDA to mass classify accessories that can be classified into Class I (similar to process used for Cures exemptions)
- Became effective 60 days after enactment (10/17/17)
- Issued guidance: Medical Device Accessories - Describing Accessories and Classification Pathways (12/20/17)

Questions from OSMA

"For the OSMA spring meeting as part of instrument classification, we would appreciate some clarity on the following topics:

• FDA's submission expectations for reclassification of orthopedic instruments from Class I to Class II based on their guidance Medical Device Accessories –

Describing Accessories and Classification Pathways.

• What product codes FDA does expect industry to use for an implant-specific accessory. Will there be new pro codes planned for introduction in 2018/2019 covering class II product codes for non-implant accessories/instruments?"

Questions from OSMA

"Can FDA provide us with a status update on the medical device accessory pathway?"

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Thank you!

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