U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Remanufacturing of Medical Devices, Final Guidance

September 10, 2024

Remanufacturing of Medical Devices Final Guidance

Frances Wilder, PhD
Regulatory Advisor
Regulation, Policy and Guidance Staff
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration

Final Guidance

- **Remanufacturing of Medical Devices**

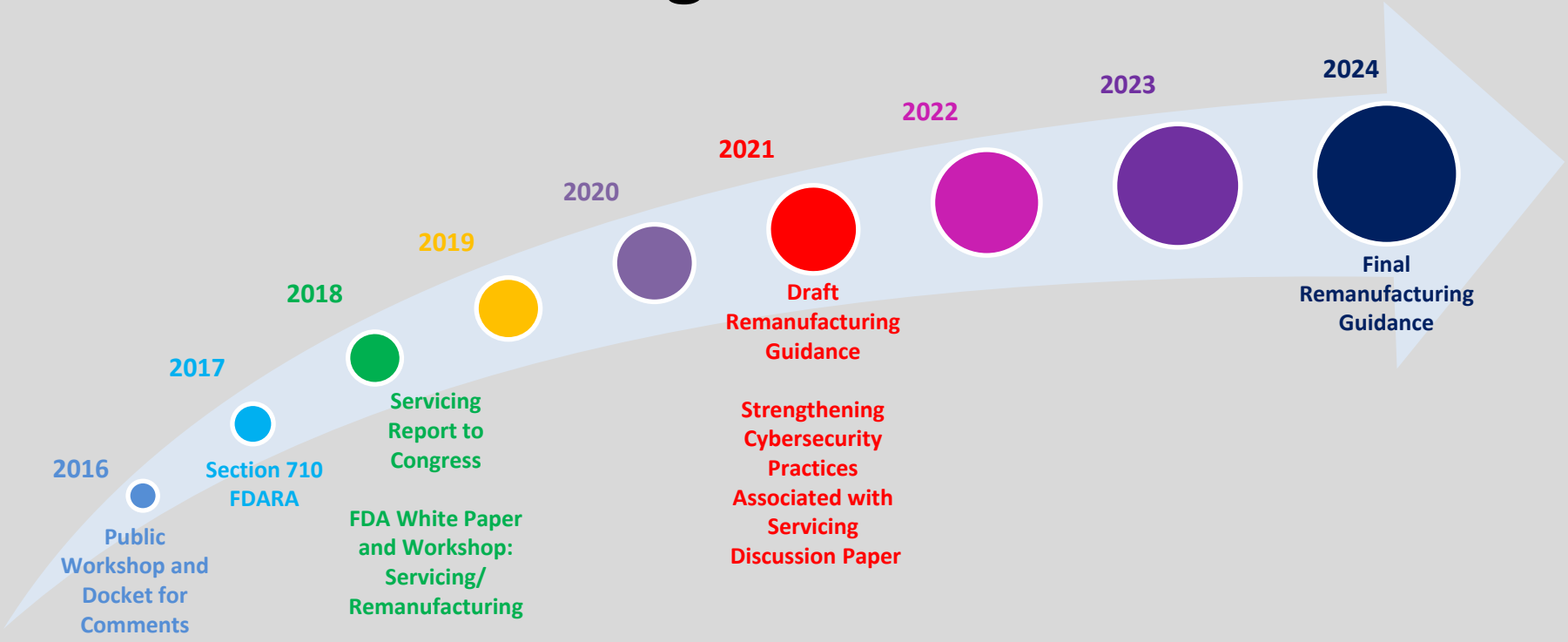
  Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff issued on May 10, 2024

  – www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

Learning Objectives

- Understand the purpose and scope of the final guidance
- Identify the guiding principles that support determining whether activities are remanufacturing
- Describe the relevant considerations for assessing activities that are likely remanufacturing
- Understand the regulatory requirements applicable to remanufacturers
- Identify information manufacturers should include in the labeling for reusable devices that are serviced

Background on Servicing and Remanufacturing of Medical Devices



Final Guidance: Purpose and Scope

Purpose of the Guidance

- To clarify the distinction between servicing and remanufacturing activities, with a focus on activities that are likely remanufacturing

Devices in Scope for the Guidance

- Devices defined in section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act, including software and electronic products that are devices
- Intended to be reused and maintained
- Irrespective of Class I, II, or III, including those subject to premarket approval

Devices out of Scope for the Guidance

- Reprocessed single-use devices

Definitions

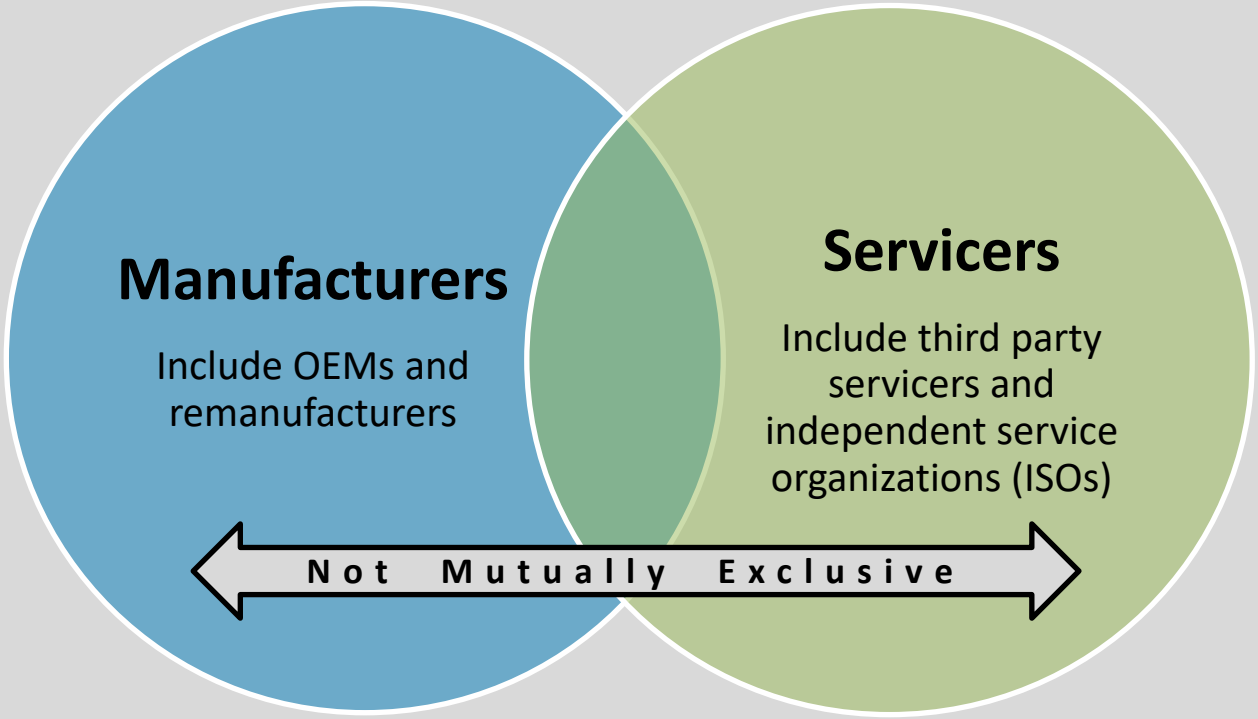
Remanufacture* - Any activity that processes, conditions, renovates, repackages, restores, or does any other act to a finished device that *significantly changes* the finished device's:

Intended Use or Performance Specifications or Safety Specifications

Service - Repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the original equipment manufacturer (OEM) and to meet its original intended use. Servicing excludes activities that significantly change the finished device's safety or performance specifications or intended use.

* See 21 CFR 820.3(w)

Entities that Perform Servicing or Remanufacturing



FDA focuses on the activities an entity performs on a particular device rather than the entity's self-identified designation.

Guiding Principles for Determining Whether Activities are Remanufacturing

1. Assess whether there is a change to the intended use
2. Determine whether activities significantly change the safety or performance specifications
3. Evaluate whether any changes to a device require a new marketing submission
4. Assess component, part, or material dimensional and performance specifications
5. Employ a risk-based approach
6. Adequately document decision-making

Relevant Considerations: What is a “significant change"?

- **Significant change to a device’s intended use** includes, but is not limited to, changing a single-use device to become reusable or changing the anatomical location of use.
- **Significant change to performance or safety specifications** is one that, based on verification and validation testing and a risk-based assessment, results in a finished device that is outside the OEM’s performance or safety specifications or introduces new risks or significantly modifies existing risks

Generally, the following changes to a finished device are most likely remanufacturing:

- Sterilization methods
- Reprocessing instructions
- Control mechanisms, operating principle, or energy type

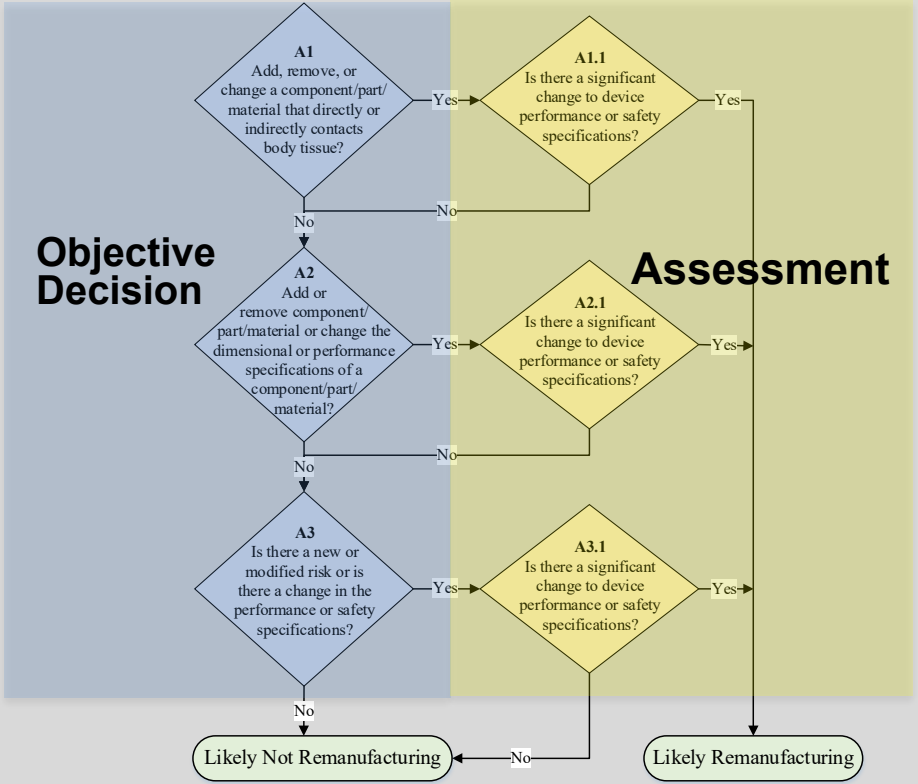
Relevant Considerations:
For changes involving components, parts, or materials

- For activities involving components, parts, and materials, FDA recommends the use of the flowchart and accompanying text in the guidance
- The flowchart **should not** be applied to software changes
- Entities performing activities on devices should determine whether each activity and the cumulative effects of such activities are remanufacturing and document their rationale

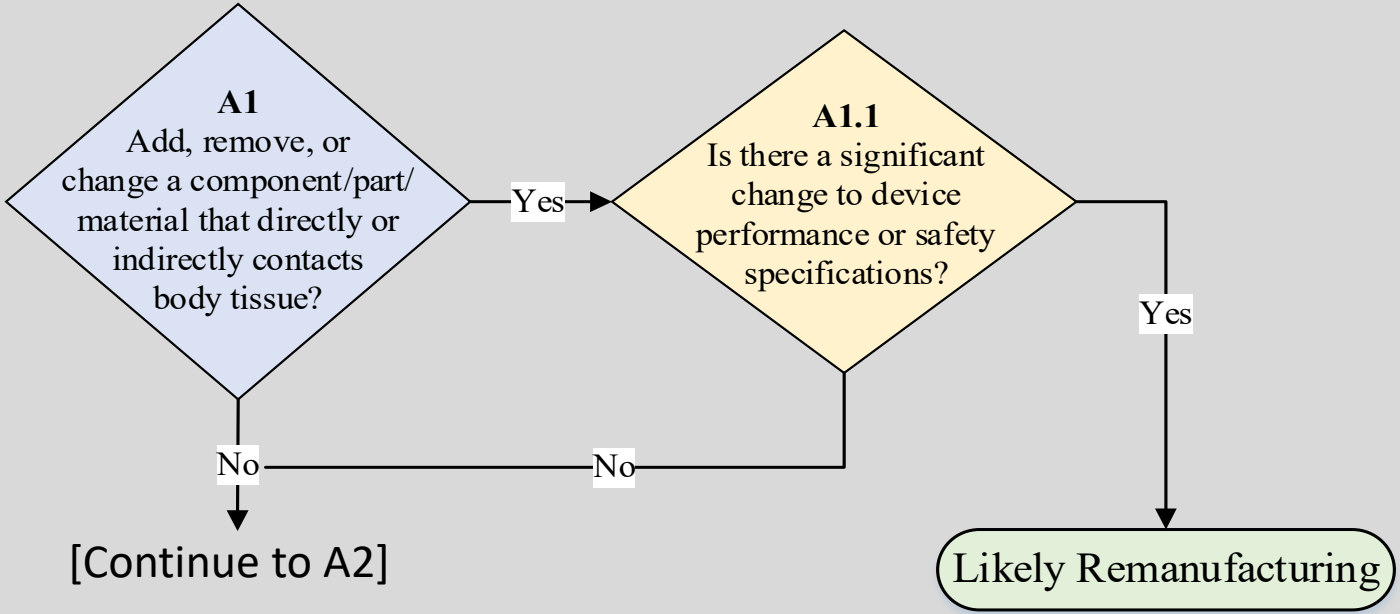
Flowchart for changes involving components, parts, or materials

- Intended to be used after an entity determines that 1) there is no significant change to intended use, and 2) no change to the device's sterilization methods, reprocessing instructions, control mechanism, operating principle, or energy type

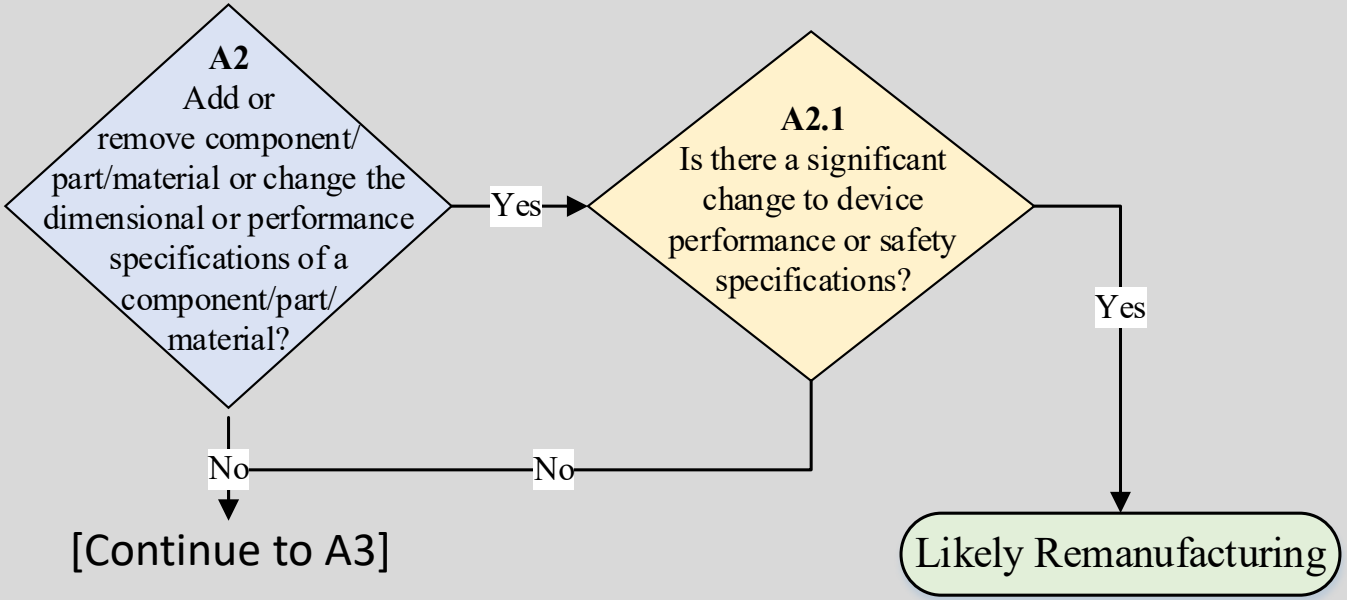
- Intended to be a visual aid but does not capture all relevant considerations. Refer to the accompanying text in the guidance.



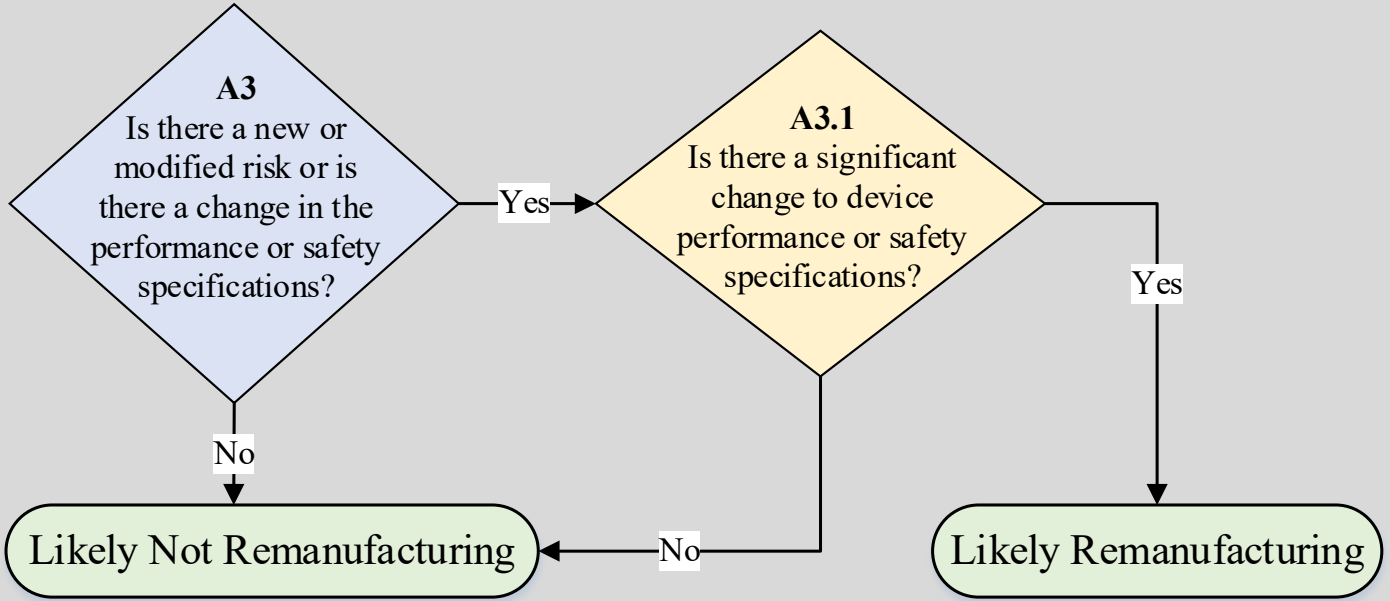
Using the Flowchart to determine if activities are likely remanufacturing



Using the Flowchart to determine if activities are likely remanufacturing



Using the Flowchart to determine if activities are likely remanufacturing



Changes Involving Software

- Flowchart should ***not*** be used for changes involving software
- Many software changes are likely remanufacturing
- FDA has identified certain activities performed on software that are likely not remanufacturing (see next slide)
- Unintended consequences and cumulative effects of any software changes should be evaluated and documented

Software Activities that are likely not Remanufacturing

Activities performed on behalf of or otherwise explicitly authorized by the OEM that return the legally marketed device to its performance and safety specifications or maintain the performance and safety specifications, and intended use

- Implementing updates and upgrades authorized, approved, or otherwise provided by the OEM
- Assessing for viruses, malware, and other cybersecurity related issues
- Reverting software to a previous configuration
- Turning on/off connectivity features (such as Wi-Fi, Bluetooth) consistent with OEM intended use
- Assessing software inventory
- Managing user accounts
- Running software-based hardware diagnostics
- Reinstalling OEM software to restore original performance and safety specifications
- Installing cybersecurity updates that are authorized by the OEM
- Performing data backup and recovery operations
- Collecting system logs
- Accessing diagnostic and repair information

Documentation Example for Remanufacturing Assessment

Remanufacturing Assessment
(Example 1)

Product: Pump ABC

UDI: (01)51022222233336(11)141231(17)150707(10)A213B1(21)1234

Date of activities performed: 12/11/2018

Date assessment completed: 12/10/2018

Description of device: Syringe pump

Description of activities performed: Replaced broken door with part #xxx

Determination of whether the activity is remanufacturing: While a change to a body contacting component, the door used was OEM-provided and is identical to the broken door. Because it is a replacement of an identical part, there are no changes to performance or safety specifications. This activity is not remanufacturing.

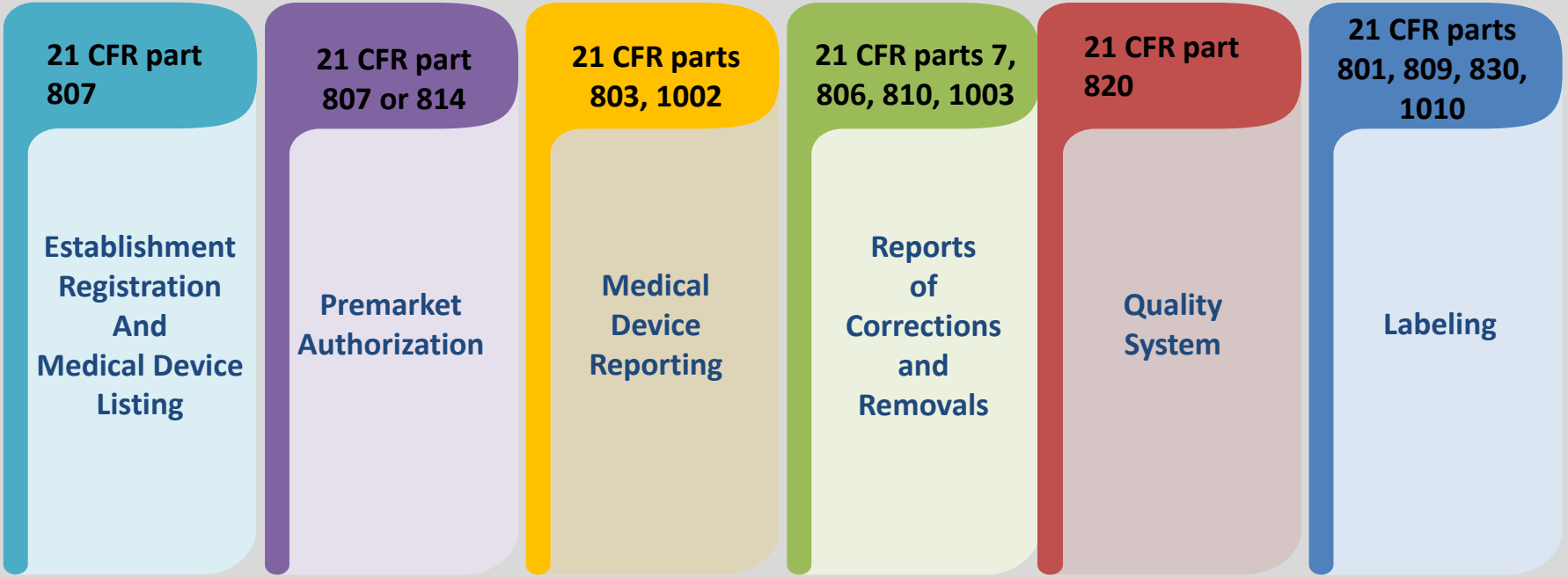
Reference to related documents supporting the decision-making process: N/A

Technician performing service: xxx

Reviewed by: xxx

Signature(s): xxx

Regulatory Requirements and Considerations for Remanufacturers



Labeling Considerations for Reusable Devices to Facilitate Routine Maintenance and Repair

- Key performance and safety specifications
- Critical technical or functional specifications
- Recommended maintenance activities and schedule
- Recommended troubleshooting steps, routine testing, and acceptance criteria
- Description of error codes, alerts, and alarm features
- Precautions, and warnings relevant to servicing the device
- Version number and release date of software

Substantive Changes from Draft Guidance to Final

- Added contextual examples of activities throughout Section VI.B to provide further clarity on whether activities remanufacture a device

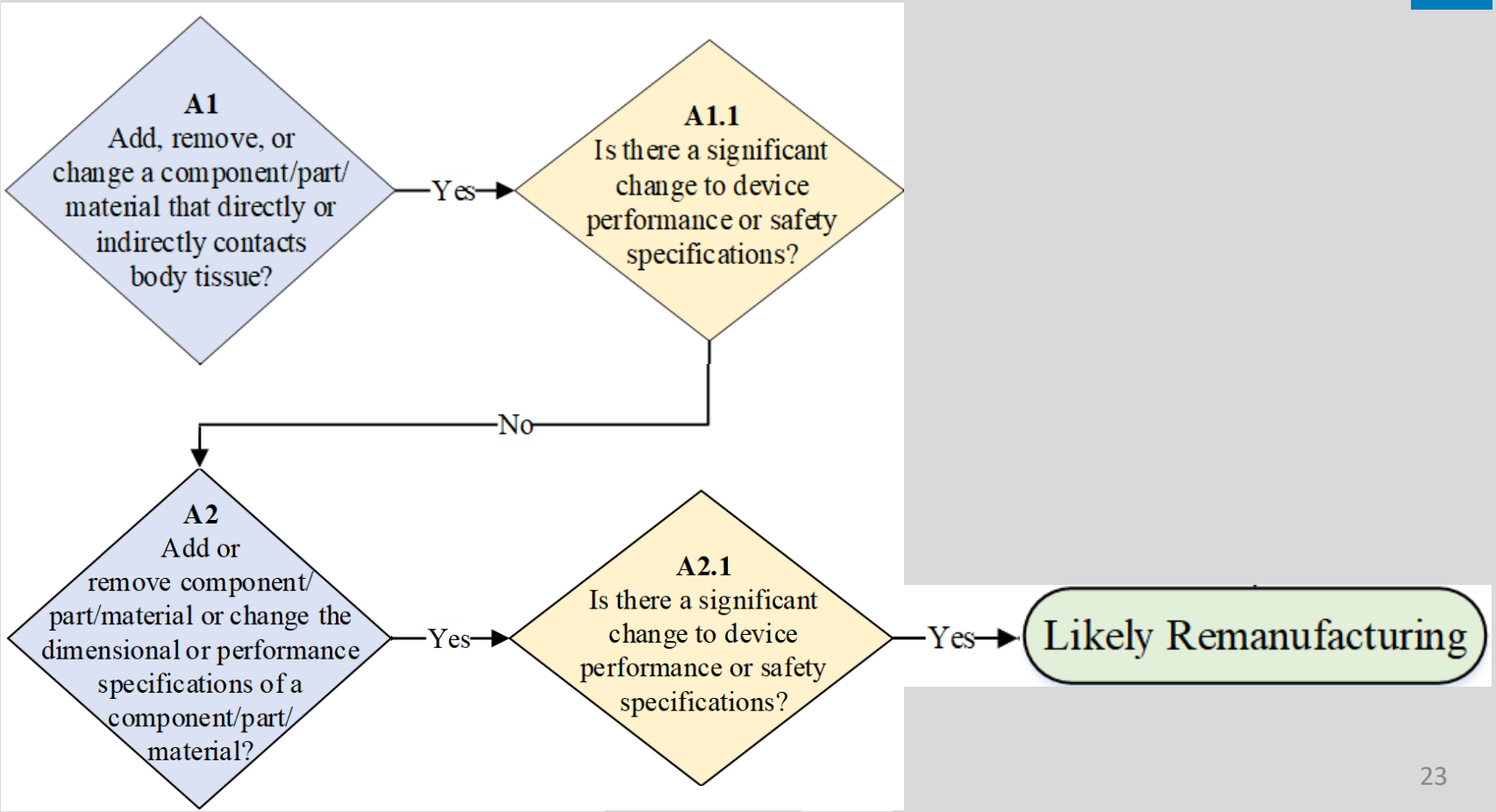
- Clarified the applicability of the guidance to OEMs and external entities acting on behalf of OEMs

- Added new section (Section VIII “Regulatory Requirements and Considerations for Remanufacturers”) to clarify the regulatory requirements applicable to remanufacturers (consistent with requirements for manufacturers)

Illustrative Example for assessing whether an activity is remanufacturing

Activity: The lens of an endoscope is cracked. The lens is affixed by an epoxy that is not described in the labeling. The cracked lens was removed and replaced. The epoxy used was purchased from the OEM and is identical to that used in the legally marketed device. The replacement lens comes from a different endoscope model from the same OEM; that model was 510(k)-cleared with improved optical performance (for example, resolution and distortion) relative to the original endoscope. The replacement lens has the same material but different optical specifications (for example, focal length and Abbe number) from the original.

Illustrative Example Continued: Using the Flowchart



Summary

- Guiding principles in Section V should be applied to determine whether activities are remanufacturing
- Relevant considerations in Section VI, including use of the flowchart, can help further assess whether certain activities are likely remanufacturing
- Existing regulatory requirements applicable to device manufacturers are also applicable to remanufacturers
- Reusable devices that undergo routine maintenance and repair should include information in the labeling to facilitate servicing

Resources

Slide Number	Cited Resource	URL
3	Remanufacturing of Medical Devices, Final Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices
5	Device Advice: Remanufacturing and Servicing of Medical Devices	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/remanufacturing-and-servicing-medical-devices
5	FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices	www.fda.gov/media/113431/download
5	Discussion Paper: Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices: Challenges and Opportunities	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/discussion-paper-strengthening-cybersecurity-practices-associated-servicing-medical-devices


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Additional Panelists

Katelyn Bittleman
Policy Analyst
Compliance and Quality Staff

Angela Krueger

Deputy Office Director for Regulatory Policy

Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

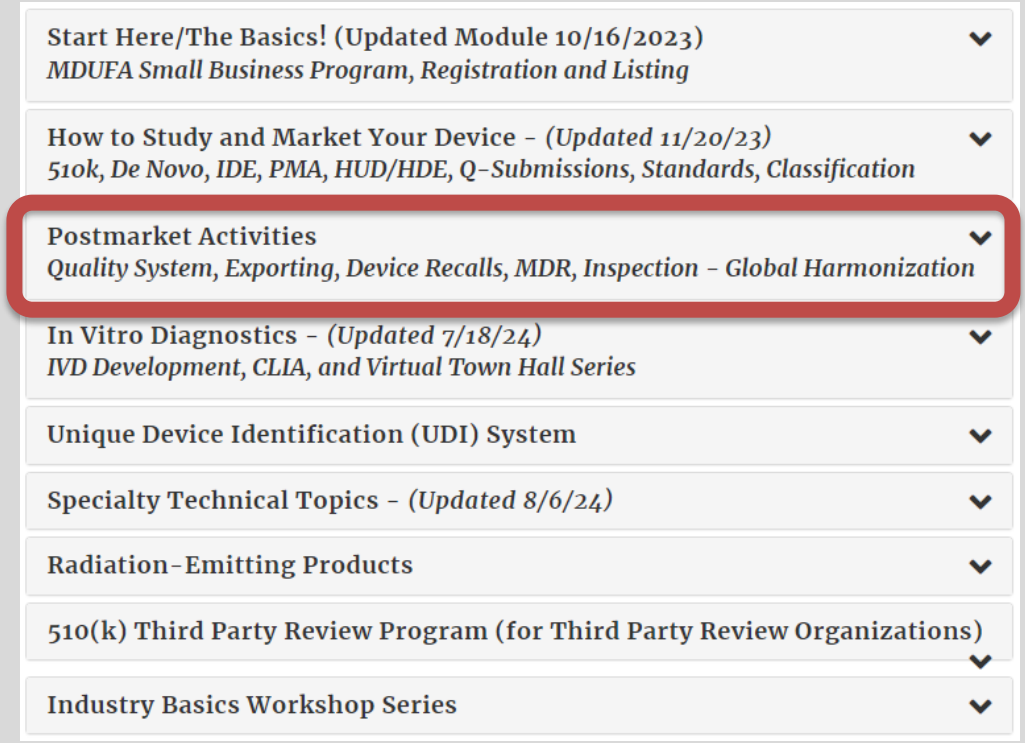
  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHEvents




FDA
U.S. FOOD & DRUG
ADMINISTRATION