

Innovative Insights into Medical Device Remanufacturing and Servicing

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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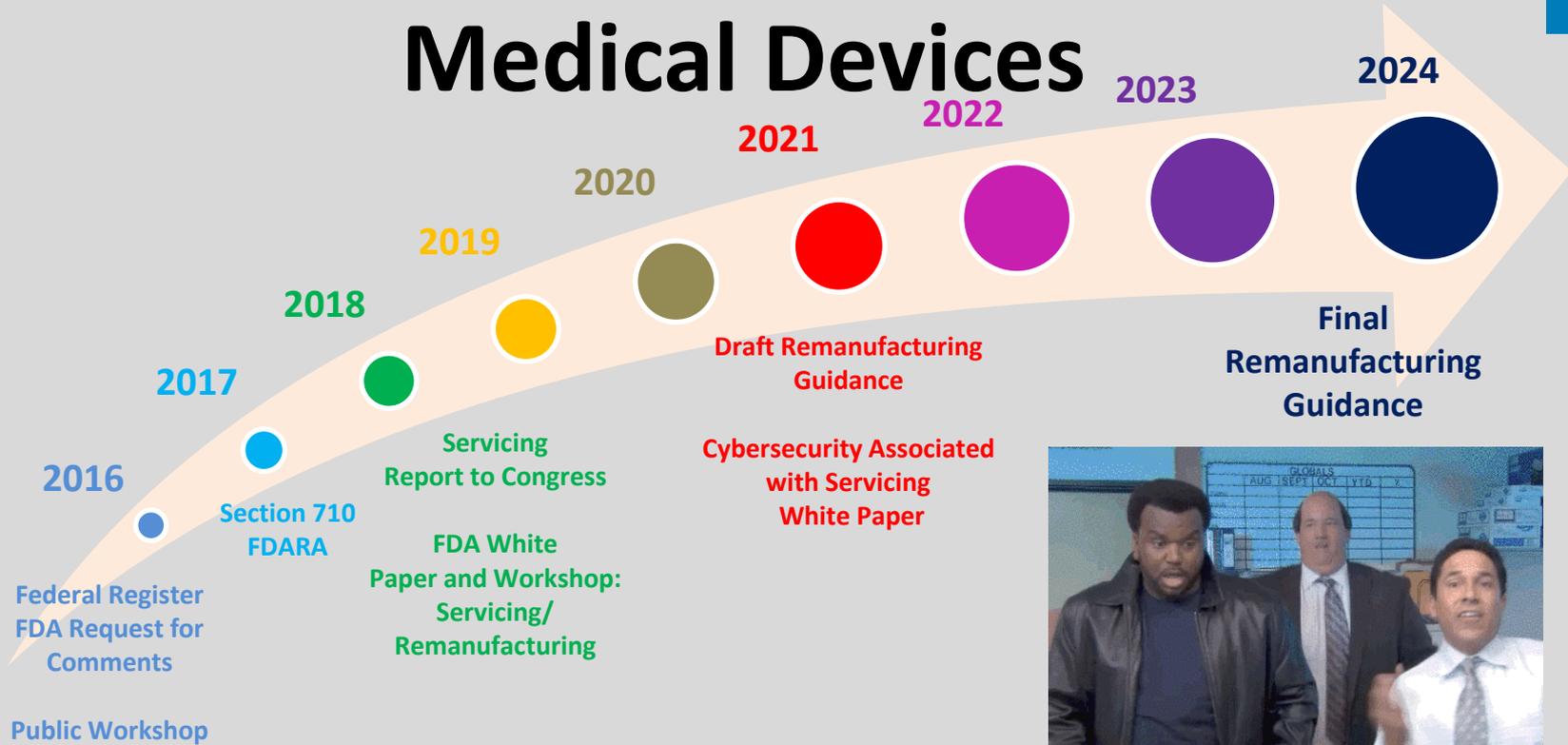
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Center for Devices and Radiological Health

U.S. Food and Drug Administration

Servicing and Remanufacturing of Medical Devices



Learning Objectives

- Explain the purpose of the final guidance “Remanufacturing of Medical Devices”
- Describe ways to identify remanufacturing activities
- Discuss considerations for labeling reusable devices to ensure quality servicing

Purpose of final guidance “Remanufacturing of Medical Devices”

Servicing Report

Promote the adoption of quality management principles

Clarify the difference between servicing and remanufacturing

Strengthen cybersecurity practices associated with servicing of medical devices

Foster evidence development to assess medical device servicing

[FDA Servicing Report](#)



Remanufacturer Definition

- 21 CFR 820.3(w)
- Any person ... that significantly changes the finished device's:

Performance
Specifications

Safety
Specifications

Intended Use

Remanufacturing of Medical Devices

Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff

Document issued on May 10, 2024.

The draft of this document was issued on June 24, 2021.

For questions about this document regarding CDRH-regulated devices, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

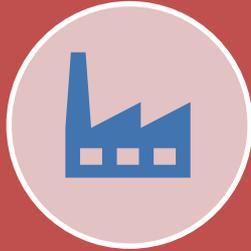


U.S. FOOD & DRUG
ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

[Guidance: Remanufacturing of Medical Devices](#)

Stakeholder Definition



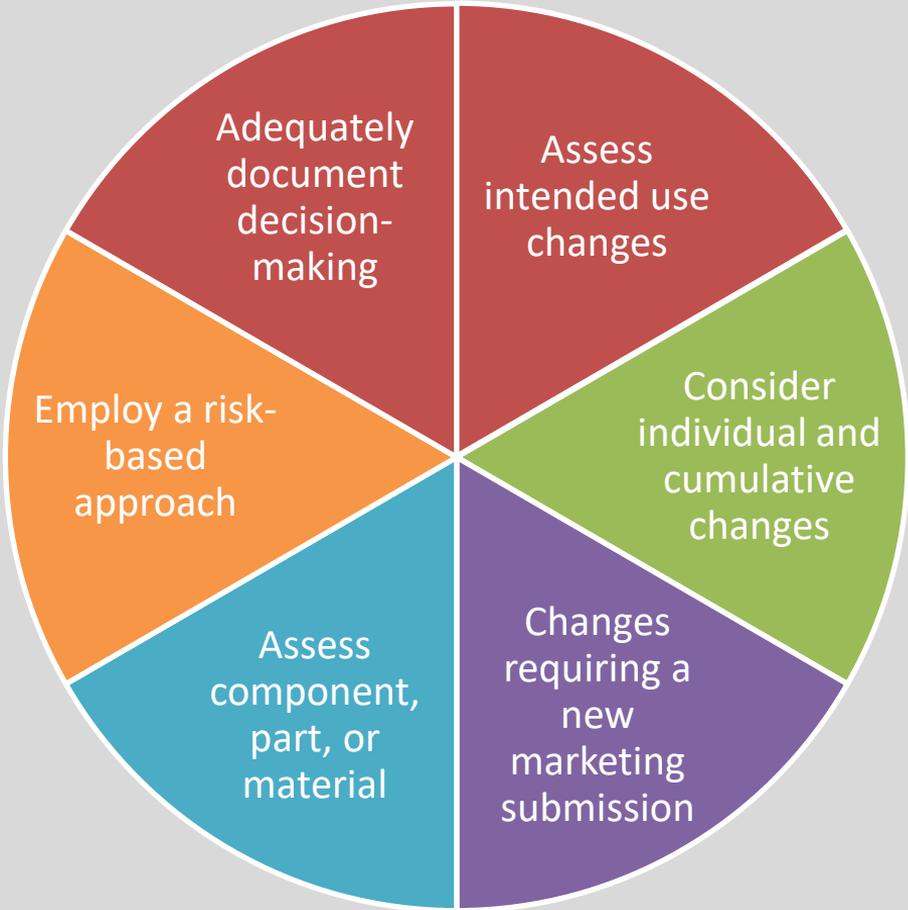
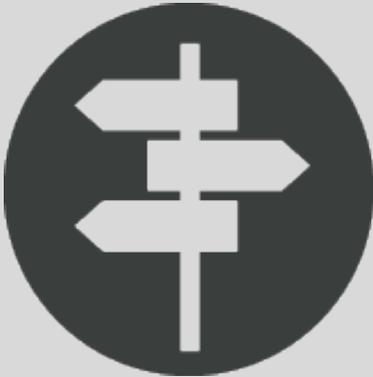
Manufacturers [Manufacturers, Original Equipment Manufacturers (OEMs), or Remanufacturers]



Third Party Servicers and Independent Service Organizations (ISOs)

Not Mutually Exclusive

Apply Guiding Principles



**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



Appendix B. Documentation Example

Identifying Remanufacturing Activities

Relevant Considerations: Determine if Significant Change

Generally, these changes to the finished device are most likely remanufacturing...

Sterilization
Methods

Reprocessing
Instructions

Control
Mechanism,
Operating
Principle, or
Energy Type

Figure 1. Flowchart

- Flowchart to help determine whether activities performed are likely remanufacturing for:
 - Components
 - Parts
 - Materials
- Used as visual aid

Figure 1. Flowchart

- Used after determining no significant change to intended use
 - Assess individual change
 - Assess cumulative effects
- Does not capture all relevant considerations
- To be used with accompanying text

Figure 1. Flowchart

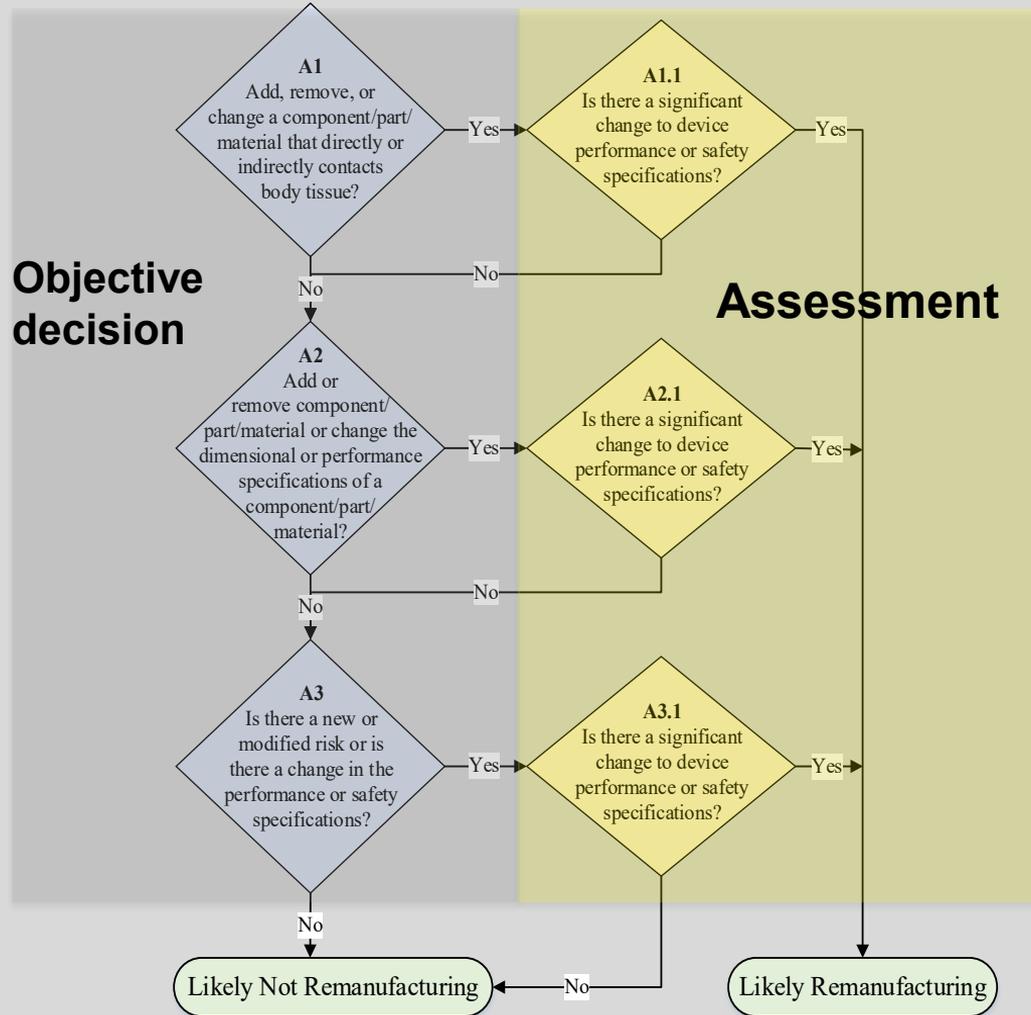


Figure 1.: A1 and A1.1

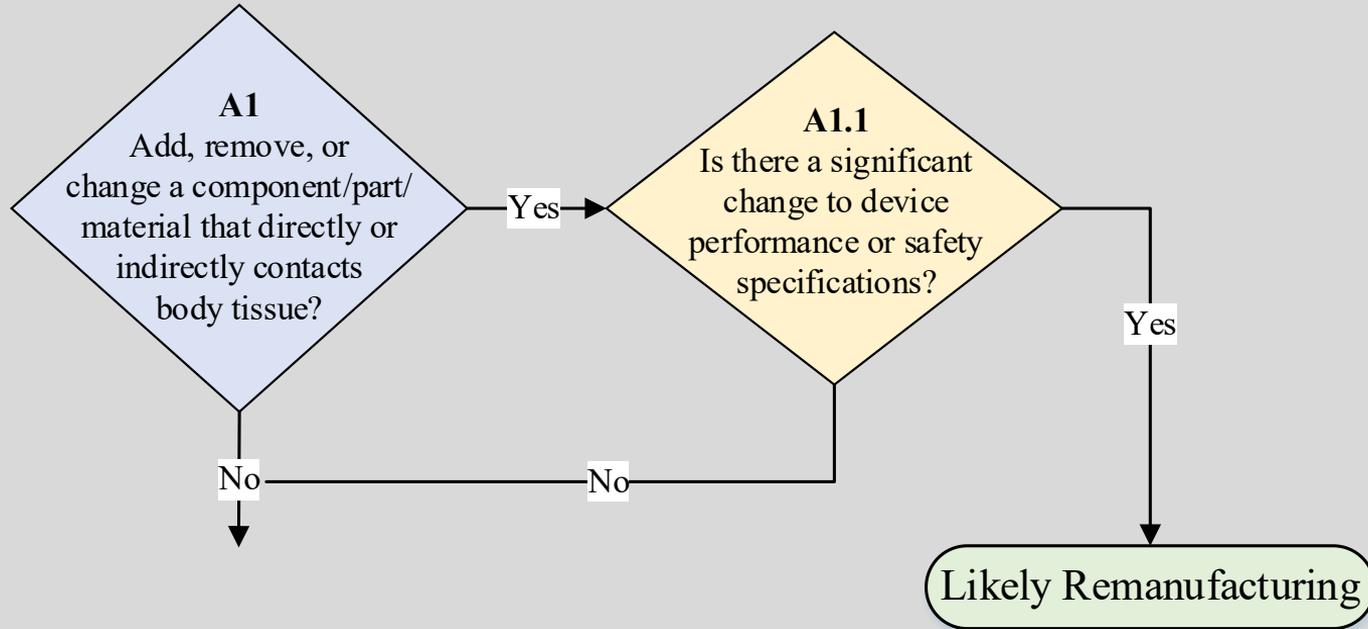


Figure 1.: A2 and A2.1

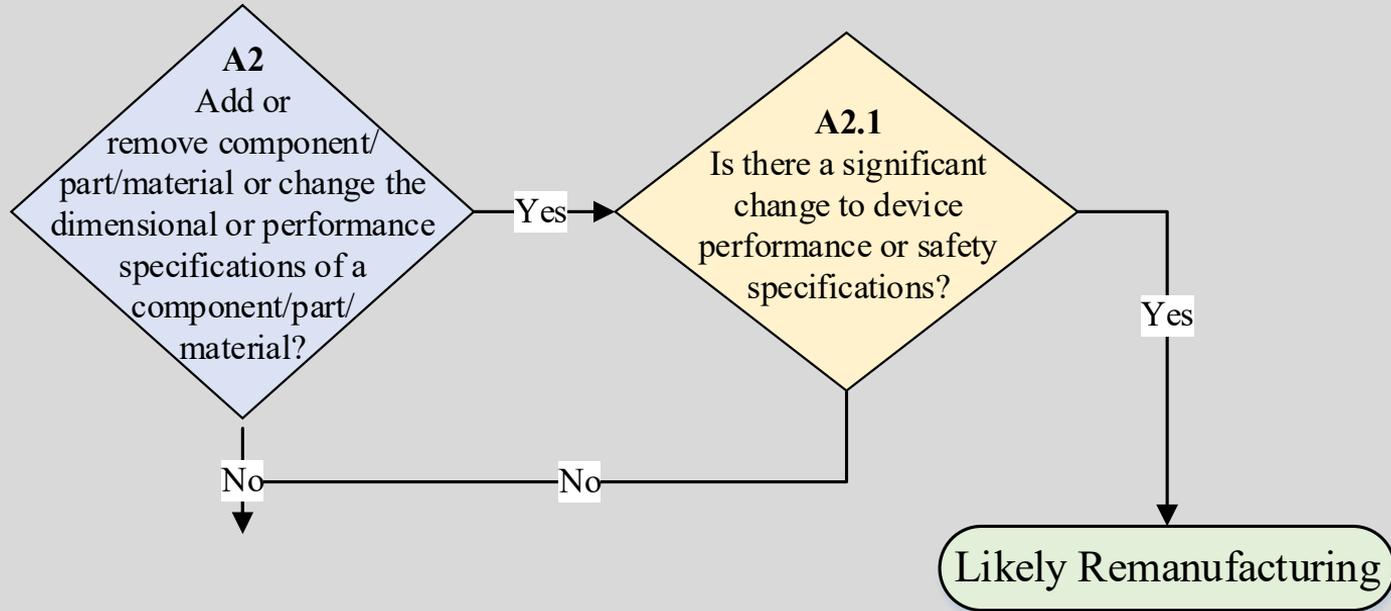
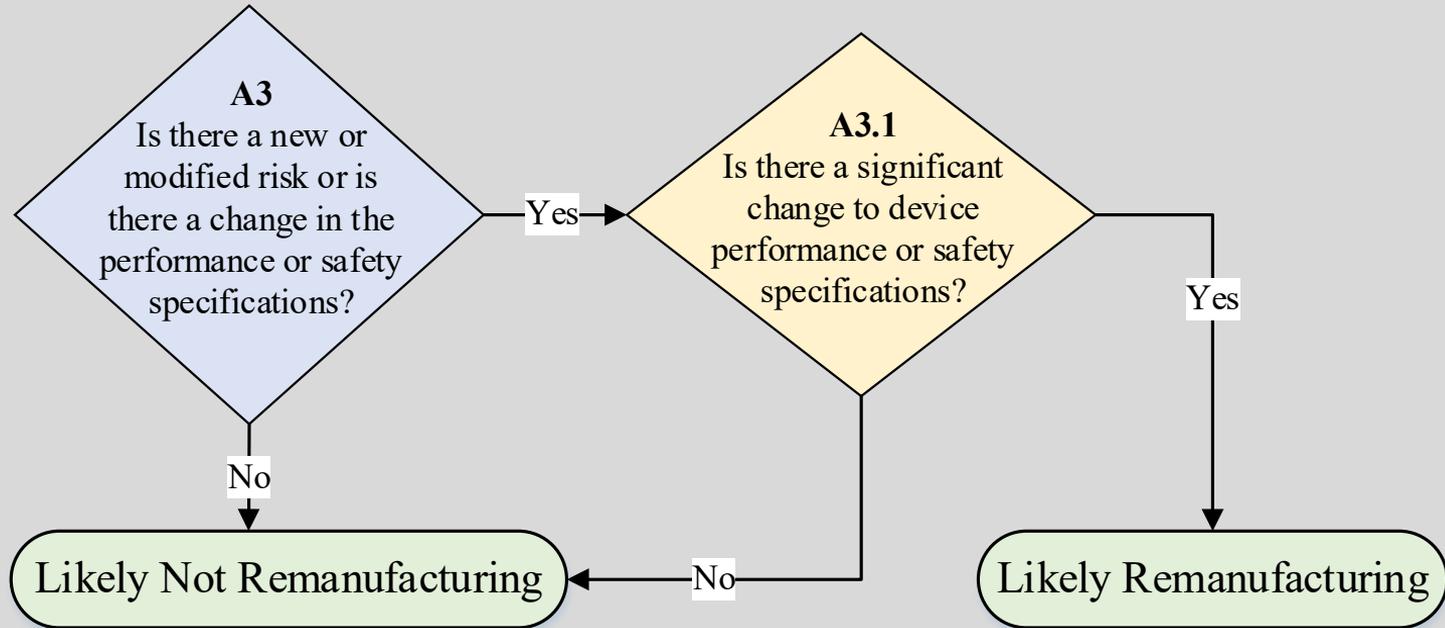
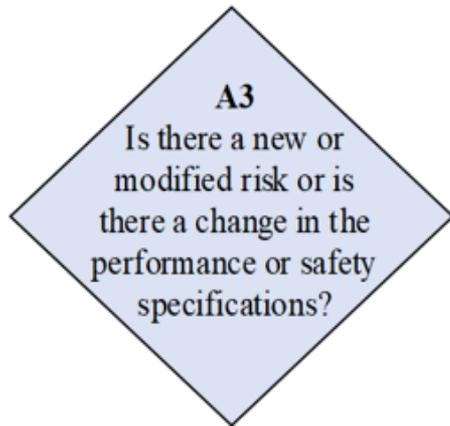


Figure 1.: A3 and A3.1



Example Scenario

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 was not purchased from the OEM. The lens was tested and demonstrated to have the same optical specifications (for example, focal length and Abbe number) and materials as the original lens.



Changes Involving Software



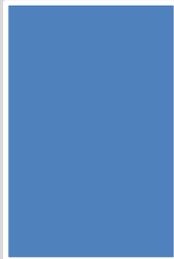
Don't use **Figure 1**. Flowchart



Many software changes are likely remanufacturing



Unintended consequences and cumulative effects of any software changes should be evaluated



Adequately document their decision-making

Remanufacturer Regulatory Requirements



Knowledge Check

What changes should Figure 1. Flowchart be used to assess?

1. Changes to components/parts/materials
2. Changes to software
3. Changes to intended use
4. All of the above

Labeling Considerations for Reusable Devices

Labeling Considerations



Key performance and safety specifications



Critical technical or functional specifications



Recommended maintenance activities and schedule



Version number and release date of software



Recommended troubleshooting steps, routine testing, and acceptance criteria



Description of error codes, alerts, and alarm features



Precautions, and warnings relevant to servicing the device

Knowledge Check

Which of the following is not a guiding principle of the final guidance “Remanufacturing of Medical Devices”?

1. Employ a risk-based approach
2. Use of non-OEM parts is remanufacturing
3. Consider individual and cumulative changes
4. Document decision making

Resources



Slide Number	Cited Resource	URL
5	FDA Servicing Report	www.fda.gov/media/113431/download
7	Guidance: Remanufacturing of Medical Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

Other Resources



Resource	URL
Remanufacturing and Service Medical Devices (Device Advice)	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/remanufacturing-and-servicing-medical-devices
Discussion Paper: Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices: Challenges and Opportunities (Device Advice)	www.fda.gov/medical-devices/quality-and-compliance-medical-devices/discussion-paper-strengthening-cybersecurity-practices-associated-servicing-medical-devices
Guidance: Postmarket Management of Cybersecurity in Medical Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices
MedWatch Forms for FDA Safety Reporting (FDA Website)	www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

Summary

- High-quality servicing is essential for a functional health-care system
- Remanufacturing is based on the **activity**, not the *entity*

Questions



Your Call to Action

1. Employ a risk-based approach to determine significance of changes.
2. Document your justification!