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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.

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

Preface

Public Comment

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Remanufacturing of Medical Devices

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

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

Medical devices encompass a vast array of products with different technologies, product lifecycles, complexity, intended users, and environments of use. Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between "servicing" and "remanufacturing" of a device. Most notably, remanufacturing has implications for the regulatory responsibilities of entities performing these activities.[1]

This guidance is intended to help clarify whether activities performed on devices are likely "remanufacturing." Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements. This guidance also includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life. In developing this guidance, FDA considered objective evidence and information learned from the Agency's activities discussed in this guidance.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled

[1] FDA's Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices (FDA Report on Device Servicing) discusses medical device servicing in more detail, available at https://www.fda.gov/media/113431/download.

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

"Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices"[3] and "Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research."[4]

In general, FDA's guidance documents 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 guidance means that something is suggested or recommended, but not required.

II. Background

FDA has been working to gain additional perspectives on the distinction between "servicing" and "remanufacturing" and has undertaken several efforts to help promote clarity. FDA opened a docket for public comment[5] and held a public workshop in 2016.[6] FDA received comments, complaints, and adverse event reports alleging inadequate servicing, which were discussed and analyzed in the FDA Report on Device Servicing,[7] published by FDA in May 2018 in accordance with section 710 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52).[8]

In the FDA Report on Device Servicing, FDA concluded that a majority of the comments, complaints, and adverse event reports received by the Agency that referred to inadequate "servicing" causing or contributing to adverse events and deaths actually pertained to "remanufacturing." This conclusion was based on FDA's evaluation of the available objective evidence[9] related to the quality, safety, and effectiveness of medical device servicing.

In 2018, FDA released a white paper, opened a public docket, and held a public workshop to facilitate public discussion on the distinction between servicing and remanufacturing.[10] The white paper described FDA's initial thoughts about guiding principles, provided a flowchart with accompanying text for understanding the distinctions, and contained a complementary approach for software, as well as considerations for labeling, and examples utilizing the flowchart. FDA

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[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.
[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation.
[5] 81 FR 11477. Public comments submitted to the docket are searchable under FDA-2016-N-0436, available at https://www.regulations.gov/docket?D=FDA-2016-N-0436.
[6] 81 FR 46694.
[7] Available at https://www.fda.gov/media/113431/download.
[8] FDA's conclusions in this report were based on the available information, which included but was not limited to the information presented at the 2016 public workshop, responses to the docket request for comments, and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing.
[9] The objective evidence evaluated in the FDA Report on Device Servicing included a numerical estimation of service and repair entities, literature review, ECRI Institute analysis, medical device reports (MDR), and complaints that FDA received.
[10] Available at https://wayback.archive-it.org/7993/20201222125933/https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-device-servicing-and-remanufacturing-activities-december-10-11-2018-12102018. FDA requested comments through docket number FDA-2018-N-3741.

also included targeted questions throughout the white paper for which the Agency sought feedback. FDA considered the comments from the public docket and discussions during the public workshop, as well as comments from the public docket on the draft guidance, in developing this guidance.

The distinction between "remanufacturing" and "servicing" is important to understand. Remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[11] For the purposes of this guidance, FDA refers to the original equipment manufacturer's (OEM's) legally marketed finished device as the "legally marketed device."

Servicing is the 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 OEM and to meet its original intended use.[12] As described in the FDA Report on Device Servicing, FDA's authority to regulate the servicing of medical devices by any entity is grounded in the Agency's authority to regulate medical devices and radiation-emitting electronic products under the Federal Food, Drug, and Cosmetic (FD&C) Act.

Irrespective of an entity's self-identified designation as a "servicer" or "remanufacturer," FDA focuses on the specific activities an entity performs on a particular device.[13] The determination of whether the activities an entity performs are remanufacturing affects the applicability and enforcement of regulatory requirements under the FD&C Act and its implementing regulations. FDA has consistently enforced requirements under the FD&C Act and its implementing regulations on entities engaged in remanufacturing, including but not limited to registration and listing, adverse event reporting, the Quality System (QS) regulation, and marketing submissions.

III. Scope

Because of the apparent confusion between servicing and remanufacturing, FDA committed in the FDA Report on Device Servicing to issue guidance that clarifies the difference between servicing and remanufacturing activities. To assist with this clarification, FDA focuses this guidance on those activities that are likely remanufacturing.

This guidance addresses activities performed on devices that are intended to be reused and maintained. This guidance discusses whether activities performed by OEMs and third parties on such devices are likely remanufacturing. This guidance is not intended to adopt significant policy changes, but to clarify FDA's current thinking on applicable definitions, and clarify, not change,

[11] See 21 CFR 820.3(w).

[12] For purposes of the report that Congress required FDA to post on its website, section 710(c) of FDARA (Pub. L. 115-52, 131 Stat. 1068) defines servicing to include, "with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, remanufacturing, or other servicing of the device." However, for purposes other than that report, FDA does *not* consider remanufacturing to be a type of servicing.

[13] The designations of servicer and remanufacturer are not mutually exclusive. An entity may meet multiple definitions based on the activities it performs on one or multiple devices. For example, an entity could be both an OEM and a third party servicer by manufacturing their own device, and servicing another entity's device, respectively.

the regulatory requirements applicable to remanufacturers. The concepts in this guidance are also not intended to alter or supersede existing regulations and policies related to the regulatory threshold for submitting a marketing submission for a device.

The products included within the scope of this guidance are devices as defined in section 201(h) of the FD&C Act, including software and electronic products that meet the definition of a device. In general, the concepts discussed in this guidance are meant to apply to all reusable devices, irrespective of their classification into class I, II, or III, including those subject to premarket approval. This guidance is not intended to address reprocessed single-use devices.

IV. Definitions

The following definitions apply for the purposes of this guidance.[14]

- Intended use: The general purpose of the device or its function, which encompasses the indications for use.[15]
- Manufacturers (Manufacturers, OEMs, or Remanufacturers): A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device.[16] A remanufacturer is any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[17] Remanufacturers are considered to be manufacturers.[18] For electronic products, a manufacturer is any person engaged in the business of manufacturing, assembling, or importing electronic products.[19]
- Performance specifications: The performance characteristics of a device established by the OEM for the device to perform as intended, including those listed in device labeling or in finished product release specifications. Some examples include measurement accuracy, output accuracy, energy output level, and stability criteria.
- Recondition/Refurbish/Rebuild: Restores a medical device to the OEM's original specifications comparable to when new. The device is brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair of components, installation of OEM provided updates and upgrades, and replacement of worn parts.

[14] Consistent with FDA's current thinking in this context, some of the definitions that appeared in the FDA Report on Device Servicing have been modified to reflect updated understanding and practice.
[15] FDA uses this term consistent with the meaning of intended uses in 21 CFR 801.4.
[16] 21 CFR 820.3(o).
[17] 21 CFR 820.3(w).
[18] 21 CFR 820.3(o) and 820.3(w).
[19] 21 CFR 1000.3(n).

- Remanufacture: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[20, 21]
- Repair: A type of servicing that returns a component to the OEM's original specifications, including replacing non-working components or parts outside of preventive or routine maintenance.
- Reprocess: With respect to reusable devices, means validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use on a patient. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.[22]
- Safety specifications: The safety characteristics of a device established by the OEM for the safe use of the device, including those incorporated into the device design and finished product release specifications, generally including the device's compensating controls and risk mitigations. Some examples include alarms, sensors, and locking or fail-safe mechanisms.
- 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 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.
- Third party servicers and Independent Service Organizations (ISOs): Entities, other than the OEM or healthcare delivery organizations,[23] that maintain, restore, refurbish, repair, or service a finished device after distribution, for purposes of returning it to the OEM's original safety and performance specifications and to meet its original intended use.

V. Guiding Principles

As outlined above, remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[24] In using this guidance to help determine whether activities are remanufacturing, FDA recommends application of the following guiding principles:

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[20] 21 CFR 820.3(w).

[21] FDA acknowledges the U.S. International Trade Commission (USITC) defines the term "remanufacturer" and similar terms in their 2012 Publication 4356 entitled "Remanufactured Goods: An Overview of the U.S. and Global Industries, Markets, and Trade." The definition in this guidance is based in FDA's regulation. USITC's definition is more analogous to this guidance's definition of "recondition/refurbish/rebuild." Additional information on the USITC's definition of "remanufacture" terms can be found here: https://www.usitc.gov/publications/332/pub4356.pdf.

[22] See the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[23] More information on the oversight and regulatory differences between ISOs and healthcare delivery organizations can be found in FDA's Report on Device Servicing, available at https://www.fda.gov/media/113431/download.

[24] 21 CFR 820.3(w).

1. **Assess whether there is a change to the intended use –** Given that the purpose of servicing is to return the device to the safety and performance specifications established by the OEM and to meet its original intended use, any change to the intended use should be evaluated to determine whether the activity is remanufacturing.[25]

2. **Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device** – Remanufacturing includes activities that significantly change the performance or safety specifications of the finished device. FDA considers "change" to also include activities that enhance the device. Activities that are not *intended to* significantly change the performance or safety specifications, however, should still be evaluated to determine whether they *do* significantly change the finished device's performance and safety specifications. Multiple changes, when considered cumulatively, may significantly change the performance or safety specifications of the legally marketed device and should be evaluated.

3. **Evaluate whether any changes to a device require a new marketing submission** – Regardless of whether changes made to a legally marketed device are remanufacturing, such changes should be evaluated to determine whether a premarket notification (510(k)), premarket approval application, or other marketing submission is required pursuant to the FD&C Act and applicable regulations,[26] and entities should consult relevant guidance for FDA's recommendations on the topic.[27] Changes that meet the definition of remanufacturing can trigger the need for a marketing submission, depending on the risk-based classification of the device. For example, a change to a device subject to 510(k) and/or special controls should be considered with respect to the criteria in 21 CFR 807.81 describing when a new 510(k) submission is required and any special controls under the relevant device classification regulation, respectively.

4. **Assess component/part/material[28] dimensional and performance specifications** – Assessment of changes to dimensional and performance specifications can inform whether the activity performed is remanufacturing. The impact of component/part/material changes can be evaluated by comparison to the OEM components/parts/materials specifications and/or through verification and validation

[25] Consistent with Guiding Principle 3, any changes that affect or change intended use should be considered pursuant to applicable regulations.
[26] See, e.g., 21 CFR 807.81 and 21 CFR 814 subpart B.
[27] See, e.g., "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device, and "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process for FDA's current thinking on these topics.
[28] 21 CFR 820.3(c) defines a component as any 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. In this guidance, "component" and "component/part/material" are used interchangeably. Due to the nature of software and firmware, consideration of whether activities involving them may be remanufacturing is discussed separately from components/parts/materials.

testing. Deviations in component/part/material specifications from the OEM's legally marketed device may result in significant changes to the device's performance or safety specifications, and may necessitate closer evaluation, such as conducting an engineering analysis, verification and/or validation testing, or a risk-based assessment, and consideration of the regulatory criteria describing when a new marketing submission is required.

5. **Employ a risk-based approach** – Entities should employ a risk-based approach, such as one that conforms to or is consistent with ISO 14971: *Medical devices – Application of risk management to medical devices*[29] when assessing whether an activity they perform is remanufacturing. For the purposes of this guidance, a risk-based assessment is based on the combination of multiple risk concepts that are important for managing the risks of medical devices. Risk estimation, risk acceptability, risk control, benefit/risk analysis, assessment of hazards and hazardous situations, and overall risk evaluation are all concepts that can be applied during these activities. The concept of risk, as defined in ISO 14971, is the combination of the probability of occurrence of harm and the severity of that harm. Although the risk terminology used in this document is primarily derived from ISO 14971, we recognize that an individual entity's terminology may differ.

   For the purposes of this guidance, a new risk is a new hazard or hazardous situation that did not previously exist for the legally marketed device. An activity performed on a device may introduce a new risk, or may modify the probability or severity of a known risk. An activity is likely remanufacturing when a risk-based assessment identifies any new risks or significant modifications to known risks, as these are likely to significantly change performance or safety specifications, in comparison to the legally marketed device.

6. **Adequately document decision-making** – When deciding whether an activity is remanufacturing or not, FDA recommends that the rationale for the determination be documented in sufficient detail, including reference to supporting verification and validation data, to explain how the determination was made. Specifically, such documentation should specify why the activities performed on the device do or do not significantly change the performance or safety specifications, or intended use of the legally marketed device. If an entity previously determined that an activity was not remanufacturing, and the same entity is performing the identical activity on the same version or model of a device, such documentation could reference previous determinations. Effective documentation can facilitate sound decision-making and evaluation of relevant factors and information such as adverse events, and provide important information for an entity to help justify their decision-making in the event that an inspection is conducted by FDA or this information is otherwise requested.

[29] In this context, ISO stands for International Organization for Standardization, an international standards development organization. See http://www.iso.org/iso/home.html for more information.

VI. Relevant Considerations to Determine if Activities are Remanufacturing

A. What is a significant change to device performance or safety specifications?

Remanufacturing is the processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[30] For purposes of this guidance, FDA generally considers a significant change to device performance or safety specifications to be one that, based on verification and validation testing and/or 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. For example, a change to a material that contacts the human body and impacts the adequacy of the OEM's validated reprocessing instructions is likely a significant change to device performance or safety specifications, and therefore, is likely remanufacturing. Conversely, replacing an internal capacitor with one that has the same specifications (e.g., same capacitance, working voltage, temperature range, materials, and footprint) is not likely to significantly change device performance or safety specifications and therefore, is likely not remanufacturing. However, many activities, such as modifying the design of a printed circuit board or temporarily breaking a seal to replace a component, may result in a significant change to safety and performance specifications and should be carefully assessed to determine if those changes are significant.

FDA has identified certain types of activities that, in general, the Agency believes significantly change the legally marketed device's performance or safety specifications:

- Changes to the device's sterilization methods;
- Changes to the device's reprocessing instructions;[31] and
- Changes to the device's control mechanism,[32] operating principle,[33] or energy type.[34]

As discussed below in Section VI.B, activities that result in these changes are likely remanufacturing, and evaluation using the flowchart and accompanying text is not recommended.

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[30] 21 CFR 820.3(w).

[31] See the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[32] For purposes of this guidance, a control mechanism is the manner by which the actions of a device are directed. One example of a control mechanism change would be a change from analog to digital control of a medical device.

[33] For purposes of this guidance, an operating principle is the mode of operation or mechanism of action through which a device fulfills (or achieves) its intended use. An example of a new operating principle would be changing the image reconstruction algorithm used in a computed tomography x-ray system from simple back projection to a new, more radiation-efficient method.

[34] For purposes of this guidance, energy type is the type of power input to or output from the device. These changes include both energy output and input changes. A change from emitting microwave energy to radiofrequency (RF) energy would be an example of an energy output change; this type of change would likely be part of a significant redesign.

B. Determining whether activities are "remanufacturing"

As discussed in Guiding Principle 1, FDA recommends that entities evaluate if their activities change the intended use of the device. Significant changes to a device's intended use[35] (e.g., changing a single-use device to become reusable, changing the anatomical location of use) are likely remanufacturing.[36]

For activities involving components/parts/materials, FDA recommends the use of the flowchart in this section (Figure 1) to help entities determine if their activities are likely remanufacturing. Although the servicing and remanufacturing definitions and guiding principles in this document apply to software, the approach described in this section should not be applied to software due to its nature and the methods used to evaluate changes to software. Instead, see Section VII for a discussion of changes involving software.

Figure 1 is a visual aid intended to be used in conjunction with the accompanying text in this section and guiding principles. Figure 1 and the accompanying text in this section are intended to address the most common and important considerations that should be evaluated, but are not meant to capture *all* potential considerations that an entity should evaluate to determine if their activities are likely remanufacturing. Rather, they are intended to guide entities in determining when they should further evaluate such activities by conducting testing or a risk-based assessment. Entities should consult Figure 1 and the accompanying text after determining that there is no significant change to intended use.

In Figure 1, each change (e.g., physical change or change to safety control) should first be assessed individually to determine whether the activity is likely remanufacturing. After evaluating each change individually, the cumulative effects should be assessed to determine whether the activities resulting in the collective changes are likely remanufacturing. The legally marketed device should be used as the basis for comparison for individual changes and the cumulative effects of such changes. When there are no deviations in the component/part/material dimensional, performance, or safety specifications from the legally marketed device's counterpart, and there are no new or modified risks or change in the performance or safety specifications of the legally marketed device, there would likely be no significant changes to the legally marketed device, in the absence of other changes such as changes involving software.

OEMs may contract with external entities to perform activities on their behalf. For OEMs performing activities on their own devices, and for entities performing activities on behalf of, or otherwise explicitly authorized by, the OEM that returns the legally marketed device to its original performance and safety specifications and intended use, FDA does not recommend evaluating their activities using Figure 1. Evaluation of the activity, consistent with Guiding Principle 3, must be performed by the OEM through their quality management system and the

[35] 21 CFR 820.3(w).

[36] For a more detailed discussion on changes to intended use, please see Section IV.D of the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

determination should be adequately documented (see 21 CFR 807.81 and 21 CFR part 820[37, 38]). The responsibility for meeting applicable statutory and regulatory requirements and for having objective evidence of meeting these requirements may not be delegated by the OEM even though the actual work may be delegated.

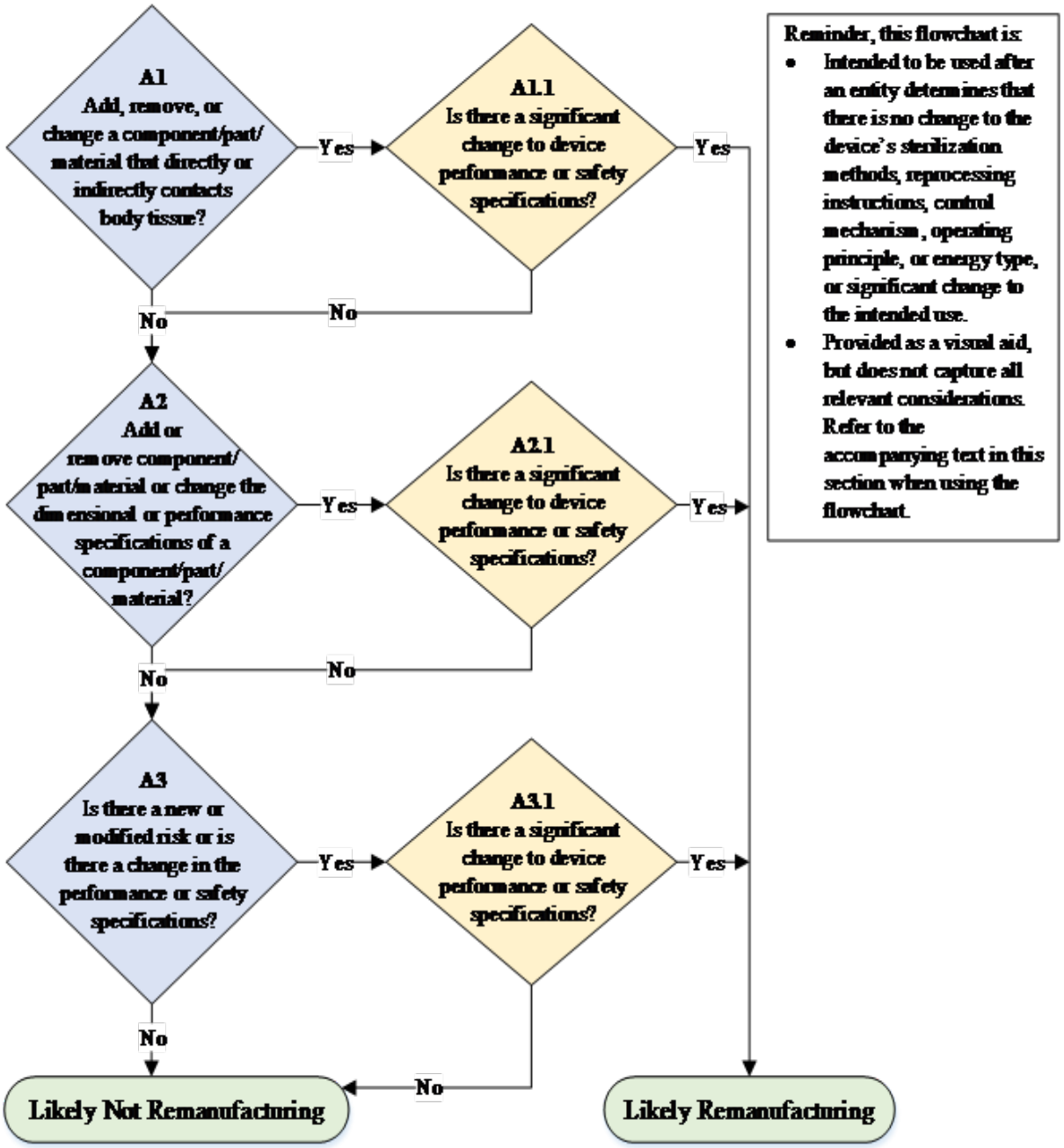
Entities performing activities on devices should make a determination about whether each activity and the cumulative effects of such activities are remanufacturing and document their rationale.[39] When deciding whether an activity is remanufacturing, entities should document the decision-making process and the basis for the determination. The documentation should be prepared in a way that clearly describes the rationale underlying the conclusion, such that it could be understood by an FDA investigator or a third party. For this, we recommend that the documentation include, at a minimum, the following:[40]

- Product name (including model number and serial number, if applicable);
- Date of activities performed, assessment, and determination;
- Description of device;
- Description of activities to be performed, including documentation of components/parts/materials involved;
- Determination of whether the activity is remanufacturing (we recommend using the applicable sections of this guidance);
- Reference to related documents supporting the decision-making process; and
- Signature(s).

FDA has included examples of such documentation in Appendix B.

[37] 21 CFR part 820 allows for manufacturers to implement a quality system that complies with requirements applicable to the operations in which it is engaged including design controls, purchasing controls, production controls, process controls, installation, or servicing as it pertains to whether an activity is remanufacturing.
[38] On February 2, 2024, FDA issued a final rule amending the device QS regulation, 21 CFR part 820, to align more closely with international consensus standards for devices (89 FR 7496, available at https://www.federalregister.gov/d/2024-01709). This final rule will take effect on February 2, 2026. Once in effect, this rule will withdraw the majority of the current requirements in part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, in part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current Part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. When the final rule takes effect, FDA will also update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.
[39] In addition, FDA notes that under 21 CFR Part 820, manufacturers are required to maintain certain records as applicable, e.g., service reports.
[40] Consistent with Guiding Principle 6, if the identical activity was previously determined to not be remanufacturing, is being performed by the same entity, and is being performed on the same version or model of a device, such documentation could reference previous determinations.

Figure 1. Flowchart to help determine whether activities performed are likely remanufacturing.



A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?

Consistent with FDA's guidance documents on reprocessing[41] and biocompatibility,[42] respectively, entities should assess how their activities may affect validated reprocessing instructions or cause an unacceptable adverse biological response resulting from device contact with the human body, including both patient and healthcare provider tissue.

Direct contact is when a component/part/material comes into physical contact with body tissue, such as catheter tubing used on a patient. A component/part/material has indirect contact when a fluid or gas passes through it prior to the fluid or gas coming into physical contact with body tissue (i.e., the device or component/part/material itself does not physically contact body tissue). For example, materials in a catheter hub (the part of the catheter that is external to the patient) indirectly contact the patient when fluids or drugs are infused through the hub and into the patient. Both direct and indirect contact with the patient or user of the device should be considered when answering A1.

If there is any addition, removal, or change to a component/part/material on the finished device, and that component/part/material directly or indirectly contacts body tissue, the answer to A1 should be "yes." This includes exposing a previously unexposed component/part/material to direct or indirect contact with body tissue. Additionally, if there is any change in material type, formulation, or chemical composition for a component/part/material that directly or indirectly contacts body tissue, the answer to A1 should be "yes." If the entity is uncertain how to respond to A1, the answer should be "yes." A "yes" answer to A1 does not necessarily mean that the activity is remanufacturing. Rather, when an entity makes such changes, it should analyze the impact of the change on the device's performance and safety specifications using the text in A1.1.

If no component/part/material added, removed, or changed directly or indirectly contacts body tissue, the answer should be "no" and then proceed to A2.

A1.1 Is there a significant change to device performance or safety specifications?

If the activity adds, removes, or changes a component/part/material that directly or indirectly contacts body tissue (as mentioned above, this includes an activity that exposes a previously unexposed component/part/material to body tissue either directly or indirectly), a risk-based assessment should be conducted. The assessment should be conducted to determine whether there is a significant change to the biocompatibility or the validated reprocessing instructions of the legally marketed device. An activity that results in such change may be considered remanufacturing.

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[41] See the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[42] See the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,'" available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

Depending on the magnitude of the change and the nature of the component/part/material, reprocessing validation and a comprehensive biocompatibility risk assessment or testing may be necessary. Entities should incorporate factors that affect the reprocessing and biocompatibility of a device in their risk-based assessment and testing where appropriate. These factors may include the materials of construction, the processing of the materials, methods (including the sterilization process), any residuals from aids used during the process, and intended use life of the legally marketed device. Activities that impact the adequacy of the legally marketed device's validated reprocessing instructions are likely remanufacturing.

If the answer to A1.1 is "yes," then the activity would likely be remanufacturing. If the answer to A1.1 is "no," then proceed to A2.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

Add or remove component/part/material? If there is any addition of a component/part/material to a legally marketed device that was not originally part of the legally marketed device, the answer to A2 should be "yes." Examples include adding an adhesive to mend a break in the device or fasteners to secure a component/part/material. If there is any removal of a component/part/material to a legally marketed device that is not replaced in the legally marketed device, the answer to A2 should be "yes." Examples include removing a fastener or barrier without replacement. Add or remove component/part/material also includes replacing an OEM component/part/material with the same OEM component/part/material or a non-OEM component/part/material.[43]

Change the dimensional or performance specifications of a component/part/material? If there is any change to or replacement of a component/part/material of the legally marketed device, which affects the component/part/material's dimensional or performance specifications, the answer to A2 should be "yes." Examples include changes to the inner or outer diameter of a tube or shaft, architecture or layout of printed circuit boards, and range of motion or articulation of components/parts/materials.

If a component/part/material is not being added or removed, or the dimensional or performance specifications of a component/part/material are not being changed, the answer to A2 should be "no." If uncertain, the answer to A2 should be "yes."

A "yes" answer to A2 does not necessarily mean that the activity is remanufacturing. Rather, when an entity makes such changes, it should analyze the impact of the change on the device's performance and safety specifications using the text in A2.1. If the answer to A2 is "no," then proceed to A3.

[43] As discussed above in Section VI.B., FDA does not recommend evaluation with Figure 1 when an activity is performed on behalf of, or otherwise explicitly authorized by, the OEM and the activity returns the legally marketed device to its original performance and safety specifications, and intended use. FDA believes such activities would likely not be remanufacturing, and the determination should be adequately documented.

A2.1 Is there a significant change to device performance or safety specifications?

Does the added or removed component/part/material significantly change the device performance or safety specifications? When evaluating whether the addition or removal of a component/part/material significantly changes the device's performance or safety specifications, the entity should consider the intended use life of the legally marketed device. For instance, many reusable devices are reprocessed numerous times within their intended use life. Applicable considerations should include an assessment of whether the added component will withstand repeated reprocessing cycles within the device's intended use life or whether the removed component exposes previously unexposed components that will withstand repeated reprocessing cycles within the device's intended use life. Such an assessment can include verification and validation testing or a risk-based assessment describing why such testing is not warranted. If the reusable device will not be able to withstand repeated reprocessing cycles within its intended use life, the addition or removal of the component/part/material may significantly change the legally marketed device's performance or safety specifications.

Do the changed dimensional specifications of the component/part/material significantly change the device performance or safety specifications? In determining whether an activity is remanufacturing for these types of changes, the entity should consider not only the magnitude of the dimensional specification change, but the criticality of the modified dimension. The entity should consider whether dimensional specifications meet a minimum or maximum specification (e.g., outer diameter cannot exceed 3.0 mm) or are within a range of acceptable tolerance specifications. If dimensional specifications are within the acceptable range, the answer to A2.1 would likely be "no;" however, for changes that are outside the acceptable range of dimensional specifications, the answer to A2.1 would likely be "yes."

Do the changed performance specifications of the component/part/material significantly change the device performance or safety specifications? When evaluating if there is a significant change to performance or safety specifications, the entity should consider whether performance outputs meet a minimum and/or maximum specification (e.g., temperature within chamber cannot exceed 25 ?C and pressure cannot be less than 150 kPa) or are within a range of acceptable tolerance specifications (e.g., pump flowrate must be between 2 and 20 mL/hour; sound of device must not exceed 65 decibels while in operation). If performance specifications are within the acceptable range, the answer to A2.1 would likely be "no;" however, for changes that result in performance specifications that are outside the acceptable range, the answer to A2.1 would likely be "yes."

If the answer to A2.1 is "yes," then the change would likely be remanufacturing. If the answer to A2.1 is "no," then proceed to A3.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?

The entity should perform a risk-based assessment to identify new or modified risks or a change in the performance or safety specifications of the legally marketed device based on the activity being performed on the device. Both the individual change and cumulative changes performed on the legally marketed device should be considered. While individual changes may not

significantly change the legally marketed device's performance or safety specifications, the cumulative changes may do so. The extent of the assessment should be appropriate considering the nature and extent of the activities being performed.

Is there a new or modified risk? A risk-based assessment can identify whether there are new risks or modified existing risks in comparison to the legally marketed device. If a new risk is created or an existing risk has been modified based on the activity being performed, the answer to A3 should be "yes," and this activity should be evaluated using the text in A3.1. If uncertain, the answer to A3 should be "yes." Examples include risk of electrostatic shock, device short circuit, or unexpected device movement.

Is there a change in the performance or safety specifications? A risk-based assessment can also identify whether there is a change in performance or safety specifications. This assessment should consider, for example, how a change could impact a device's continued conformity to a voluntary consensus standard or compliance with a regulation, such as special controls identified in a device classification regulation. This assessment should also consider whether activities that break a seal or barrier can adequately return the device to its legally marketed performance and safety specifications, including its ability to be adequately reprocessed. If a change to performance or safety specifications has been identified, the answer to A3 should be "yes." If uncertain, the answer to A3 should be "yes."

When an entity makes a change that has a "yes" answer to A3, the entity should analyze the impact of the change on the device's performance and safety specifications using the text in A3.1. If the answer to A3 is "no," then the change is likely not remanufacturing.

A3.1 Is there a significant change to device performance or safety specifications?

If new or modified risks were identified, the entity should evaluate whether they significantly change the legally marketed device's performance or safety specifications using the output of the risk-based assessment performed in A3. Removing, modifying, or bypassing a safety feature (e.g., fuses, alerts, alarms, interlocks) likely significantly changes the legally marketed device's performance or safety specifications. Changes that impact compliance with a regulation or alter conformity with a voluntary consensus standard would likely significantly change the legally marketed device's performance or safety specifications and may also adulterate and/or misbrand the device.[44]

If the answer to A3.1 is "yes," then the change would likely be remanufacturing. If the answer to A3.1 is "no," then the change is likely not remanufacturing.

VII. Changes Involving Software

As described in Section VI, Figure 1 and its accompanying text should not be applied to changes involving software. Many software changes are likely remanufacturing because of their impact on a product's software architecture, software requirements specifications, unresolved anomalies,

[44] See, e.g., sections 501(e)(2) and 502(o) of the FD&C Act.

and other key characteristics. Further, because the probability of a software failure cannot be determined using traditional statistical methods, the risk-based assessment approach that FDA recommends in Section VI should not be applied to software changes. Instead, FDA has identified certain activities performed on software that are likely not remanufacturing because they generally do not significantly change the performance or safety specifications of the device:

- 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;
- Running software-based hardware diagnostics;
- Assessing for viruses, malware, and other cybersecurity related issues;
- Reinstalling OEM software to restore original performance and safety specifications;
- Reverting software to a previous configuration;
- Installing cybersecurity updates that are authorized by the OEM;[45]
- Turning on or off connectivity features (e.g., Wi-Fi and Bluetooth connections) consistent with OEM intended use;
- Performing data backup and recovery operations;
- Assessing software inventory;
- Collecting system logs;
- Managing user accounts; and
- Accessing diagnostic and repair information.

Other activities involving changes to software are likely to significantly change a device's performance or safety specifications, such that the activity is likely remanufacturing. However, if an entity believes that an activity involving a change to software does not significantly change a device's performance or safety specifications, the entity should adequately document its decision-making (see Guiding Principles 5 and 6). Any activity involving software changes that significantly modifies a device's intended use would be remanufacturing.[46]

Entities should also consider the unintended consequences and cumulative effects of any software change(s). Entities performing activities on devices should make a determination about whether each activity and the cumulative effects of the changes resulting from the activities are remanufacturing and document their rationale.

[45] We recognize that the cybersecurity landscape rapidly evolves. FDA recommends referring to FDA's website at https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity for updates on statutory and regulatory requirements and related information.
[46] See 21 CFR 820.3(w).

VIII. Regulatory Requirements and Considerations for Remanufacturers

As stated above, remanufacturers[47] are considered manufacturers under the FD&C Act and FDA's regulations,[48] and are thus regulated as such. Entities that are remanufacturing devices, including devices that they did not originally manufacture, are generally subject to the same regulatory requirements as the OEM of the device. Basic regulatory requirements (general controls) that manufacturers of medical devices distributed in the U.S. must comply with, unless exempted by regulations, include, but are not limited to: Establishment Registration and Medical Device Listing (21 CFR part 807), Medical Device Reporting and Notification (21 CFR parts 803, and 1002) requirements, Recalls and Reports of Corrections and Removals (21 CFR parts 7, 806, 810, and 1003), Quality System (QS) Regulation (21 CFR part 820), and Labeling requirements (21 CFR parts 801, 809, 830, and 1010).[49, 50] Many device types also require premarket review, including premarket notification (also known as 510(k)) (21 CFR part 807) or premarket approval (PMA) (21 CFR part 814), depending on their device classification and other factors. Certain devices have additional regulatory requirements such as compliance with special controls, which are usually specific to devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device.[51] Unique considerations for remanufacturers for complying with these regulatory requirements are described below.

Registered remanufacturers and entities engaged in remanufacturing are subject to investigations and inspections to ensure compliance with the FD&C Act.[52] In planning and conducting inspections of medical device facilities, the Agency considers risk-based factors consistent with the FD&C Act to allocate resources effectively to carry out the Agency's mission of protecting and promoting public health.[53] When a medical device manufacturer, including a remanufacturer, fails to comply with the FD&C Act and its implementing regulations, FDA has the authority to respond with enforcement tools. In most cases, the manufacturer will take voluntary action to correct any violations identified by FDA to avoid the need for enforcement actions.

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[47] The considerations in this section apply to OEMs, third party servicers, and ISOs. The intent of this section is to provide additional insights for entities that may be less familiar with the FDA's medical device regulatory requirements.

[48] E.g., 21 CFR 820.3(o) and 21 CFR 820.3(w).

[49] For additional information regarding basic regulatory requirements for device manufacturers, see FDA's website, "Overview of Device Regulation," available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation.

[50] For additional information regarding regulations and requirements specific to radiation-emitting devices, see FDA's website, "Radiation-Emitting Products," available at https://www.fda.gov/radiation-emitting-products.

[51] For additional information regarding Special Controls and Premarket Approval for device manufacturers, see FDA's website, "Regulatory Controls" available at https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.

[52] See sections 510(h)(1), 702, and 704 of the FD&C Act.

[53] See section 510(h)(4) of the FD&C Act for the risk-based factors FDA considers during inspectional planning.

A. Establishment Registration and Medical Device Listing

Under 21 CFR part 807, owners or operators of establishments that are involved in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use in the U.S. are generally required to register annually with FDA. Generally, establishments that are required to register with FDA are also required to list their devices and the activities that are performed on those devices. As manufacturers, remanufacturers of medical devices[54] are also required to obtain their own device listing, independent of OEM's device listing, and their own establishment registration if not already registered as a device manufacturer.[55]

B. Marketing Authorization

The risk of the device determines the regulatory controls needed to provide a reasonable assurance of safety and effectiveness. Medical devices are classified into class I, II, and III with increasing regulatory controls. The class to which a device is assigned determines, among other things, the type of premarket submission or application that is required for FDA authorization to market. Most class I devices, which includes devices with the lowest risk, are exempt from premarket notification (i.e., 510(k) Exempt); class II devices require premarket notification (i.e., a 510(k)) unless exempt by regulation; and class III devices (those that are the highest risk) require premarket approval (i.e., a PMA). Remanufacturers are responsible for complying with premarket requirements, including obtaining the required FDA marketing authorization prior to conducting remanufacturing activities on the OEM's legally marketed finished device.[56] The relevant regulatory standard must be met for remanufactured devices, which have experienced a significant change to performance or safety specifications, or intended use, as compared to the OEM's legally marketed finished device. For example, for remanufactured devices requiring a 510(k), the remanufacturer must demonstrate that the device is "substantially equivalent" to a legally marketed predicate device in terms of intended use, technological characteristics, and performance testing, as needed. For remanufactured devices requiring a PMA, the remanufacturer must provide valid scientific evidence demonstrating a reasonable assurance of safety and effectiveness for the device's intended use.

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[54] As noted in Section II of this guidance, FDA focuses on the specific activities an entity performs on a particular device when determining whether an entity is the remanufacturer of the device and not on the entity's self-identified designation.

[55] For additional information on who must, when to, and how to register and list, see FDA's website "Device Registration and listing," available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

[56] Remanufactured devices may require different regulatory controls from the OEM's legally marketed finished device to provide a reasonable assurance of safety and effectiveness. Remanufacturers must identify the correct classification for the device to understand and comply with the applicable regulatory controls. For additional information on premarket submissions, see FDA's website "How to Study and Market Your Device," available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.

C. Medical Device Reporting and Electronic Product Reports

The Medical Device Reporting (MDR) regulation (21 CFR part 803) contains mandatory requirements for manufacturers, distributors, importers, and device user facilities to report certain device-related adverse events and product problems to FDA. 21 CFR part 1002 sets forth the requirements for records and reports that must be kept and submitted for certain electronic products. Manufacturers, including remanufacturers, are required to report to FDA when they learn that any of their devices may have caused or contributed to a death or serious injury.[57] Manufacturers must also report to FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[58] As manufacturers, remanufacturers also are responsible for reporting adverse events and certain malfunctions, as further defined and outlined in 21 CFR parts 803 and 1002, regarding their remanufactured device to FDA.

D. Reports of Corrections and Removals and Notifications of Defects

Under 21 CFR part 806, Medical Device Reports of Correction and Removals, manufacturers and importers are required to submit a written report to FDA of any correction or removal of medical devices if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health.[59] Even if a remanufacturer is not required to report a correction or removal of a device to FDA under 21 CFR 806.10, records of such actions must be kept.[60] Under 21 CFR part 1003, Notification of Defects or Failure to Comply, manufacturers, assemblers, and importers of electronic products who discover a defect or that the product otherwise fails to comply with applicable standards, are required to submit written notification to the FDA, and when applicable, affected persons.[61]

Firms may also choose to voluntarily report under 21 CFR part 7 if it conducts a recall, which is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.[62] A recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the

[57] See 21 CFR 803.50 and part 1002.
[58] For more information, see FDA's guidance, "Medical Device Reporting for Manufacturers," available at https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities.
[59] See 21 CFR 806.10(a). However, no report is required if the information has already been submitted to FDA under 21 CFR part 803 (Medical Device Reporting) or 21 CFR part 1004 (Repurchase, Repairs, or Replacement of Electronic Products.
[60] See 21 CFR 806.20.
[61] See 21 CFR 1003.10. However, no notification is required if the information has already been submitted to FDA under 21 CFR part 803 (Medical Device Reporting). Electronic devices subject to notification under 21 CFR 1003.10(b) are also subject to requirements under 21 CFR part 1004.
[62] See 21 CFR part 7.

request of FDA.[63] 21 CFR part 7 provides guidelines so that responsible firms may conduct an effective recall, including information to report to FDA and communicating about the recall. In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR part 810, Medical Device Recall Authority.[64] As manufacturers, remanufacturers are responsible for taking action and reporting to FDA any correction or removal which was initiated to reduce a risk to health posed by the device or to remedy a violation of the Act caused by the device which may present a risk to health.

E. Quality System

The QS Regulation (21 CFR part 820) includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices.[65] Remanufacturers of medical devices are required to have a quality system in place for their device, unless the device is exempt from good manufacturing practices (GMP) requirements.[66]

F. Labeling

Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.[67] General device labeling requirements are found in 21 CFR part 801. Additional labeling requirements for in vitro diagnostics (IVDs) are found in 21 CFR part 809 and labeling requirements for electronic products are found in 21 CFR part 1010. Unique device identification (UDI) labeling requirements are found in 21 CFR part 830.[68] Remanufactured devices most likely already have labeling associated with them that is provided by the OEM of the finished device. Remanufacturing activities that significantly change the performance or safety specifications of a device, or its intended use, are likely to require corresponding labeling changes. For example, if a remanufacturer adds a feature or function to a reusable device, such modification would necessitate labeling changes to provide adequate instructions for how to use the new feature or function and to the associated reprocessing instructions to ensure the device

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[63] For additional information on medical device recalls and corrections and removals, see FDA's website "Recalls, Corrections and Removals (Devices)," available at https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices.

[64] 21 CFR part 810 describes the procedures FDA will follow in exercising its medical device recall authority under section 518(e) of the FD&C Act.

[65] For additional information and resources on the Quality System regulation, see FDA's website "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices," available at https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices.

[66] FDA has determined that certain types of medical devices are exempt from GMP requirements. These devices are exempted by FDA classification regulations published in the Federal Register and codified in 21 CFR 862 to 892. Exemption from the GMP requirements does not exempt manufacturers of finished devices from keeping complaint files (21 CFR 820.198) or from general requirements concerning records (21 CFR 820.180).

[67] Section 201(m) of the FD&C Act.

[68] For additional information on the UDI System including the Global Unique Device Identification Database (GUDID) submission requirements, see FDA's website "Unique Device Identification System (UDI System)," available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

can be reused safely and effectively with the new feature or function. It is the responsibility of the remanufacturer to modify and validate any necessary labeling changes that are associated with the specific remanufacturing activity including, but not limited to, the remanufacturer identifying information, obtaining a new UDI, and modifying directions for use, device specifications, and warnings as needed.[69]

IX. Considerations for Labeling

Based on publicly available information and FDA's activities discussed in Section II of this guidance, FDA believes that OEMs of reusable devices intend for their devices to routinely undergo both preventive maintenance and repair. It is important that such devices include instructions on how to adequately return a device to its performance and safety specifications established by the OEM.[70] Unintentional remanufacturing can occur when entities do not have the instructions necessary to return a device to its original performance and safety specifications. The lack of adequate servicing instructions can also create challenges in the availability of quality, safe, and effective devices.

Consistent with promoting and protecting the public health, FDA encourages OEMs, as an industry best practice, to provide servicing instructions that facilitate routine maintenance and repair of their reusable devices. FDA's recommendations are not intended to encourage the disclosure of trade secrets or confidential commercial information. The OEM labeling of reusable devices should include at least the following information, as applicable, to facilitate routine device maintenance and repair:

- A description of the key performance and safety specifications;
- Critical technical or functional specifications, including:
  - Physical dimensions;
  - Electrical characteristics, including batteries (e.g., chemistry, amperage, voltage, rechargeability), internal fuses, and power supply (e.g., voltage, amperage, frequency); and
  - Device-specific performance specifications (e.g., flow rate accuracy or range, humidity, temperature, wavelength).
- The recommended maintenance activities and schedule;
- Recommended troubleshooting steps, routine testing, and acceptance criteria to confirm that the device remains within its performance and safety specifications;
- A description of error codes, alerts, and alarm features on the device;

[69] See sections 502(a), 201(n), 502(c), and 502(f)(2) of the FD&C Act. A device shall be deemed misbranded if, among other things: its labeling is false or misleading; its labeling does not contain adequate warnings; or any information required to be in the labeling is not prominently placed with such conspicuousness and in such terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[70] Section 502(f)(1) of the FD&C Act requires that labeling bear adequate directions for use. For non-prescription devices, adequate directions for use include instructions on preparing a device for use. 21 CFR 801.5(g). Prescription devices are exempt from the adequate directions for use requirement provided certain conditions are met, including that the labeling bear "information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended…" 21 CFR 801.109(c).

- Precautions, and warnings relevant to servicing the device; and
- Version number and release date of software.

Appendix A. Examples

The following are illustrative examples of activities that may be performed on devices with explanations about why such examples are or are not likely remanufacturing. Note that these generalized examples do not necessarily account for every possible detail, risk, or consideration that an entity should evaluate, and should not be taken to mean that the changes described are or are not definitively remanufacturing. Real-world decisions will depend on the specific facts and circumstances, including the specific details of the changes made to the specific device. FDA recommends referencing the guiding principles when considering the examples to expand understanding. For example, when reviewing the activities outlined in the examples below, it may be helpful to consider whether the activity results in changes to a device that would require a new marketing submission (consistent with Guiding Principle 3) and how a risk-based approach, such as ISO 14971: *Medical devices – Application of risk management to medical devices* may be instrumental in assessing risk (consistent with Guiding Principle 5).

(1) Component/part/material activities

Example E.1

Activity: The door of an infusion pump was bent and now pinches the administration set. The flow rate accuracy fell outside the OEM's specified accuracy range. The door is replaced with a non-OEM door that is marketed as compatible with this infusion pump. It has the same overall dimensions and is made from a similar material of construction. However, the replacement door material is more rigid than the original door.

Relevant questions:

A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?

No. The existing and replacement doors do not have direct or indirect contact with the patient's body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

Yes, the old door was removed and replaced. While the new door is marketed as compatible, all dimensions were confirmed through comparative measurement, including the hinges and latch. The specific material of the original door is unknown and there is a noticeable difference in flexibility that may impact the pump's performance specifications.

A2.1 Is there a significant change to device performance or safety specifications?

No. Once replaced, the door was confirmed to open and close with similar effort as the original door and it was confirmed that the added rigidity did not significantly change the pump's performance or safety specifications (e.g., flowrate accuracy).

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
No. A risk-based assessment determined that there are no new or modified risks and there is no change in performance or safety specifications (e.g., the change does not alter conformity to a voluntary consensus standard or compliance with a regulation).

Decision: Not Remanufacturing.

Example E.2

Activity: The rotor within a peristaltic infusion pump no longer functions as intended and is replaced. The subject pump rotor is no longer supported by the OEM, but a comparable off-the-shelf rotor is available. The dimensions of the rotor, including the individual rollers, are the same; however, the material of construction of the rollers, which contact and apply pressure to the administration set, appears to be stainless steel. This is different from the plastic rollers in the legally marketed device.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. Neither the existing or replacement component directly or indirectly contact body tissue. It is only in contact with the outside of the administration set.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The rotor was removed and replaced. Also, although the dimensional specifications of the non-OEM pump rotor, including the individual rollers, are the same as the OEM rotor, the roller materials are different.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. Once the rotor was replaced, the device appears to function adequately. The change in material of the rollers does not significantly change the accuracy of the flowrate across the labeled flowrate range. However, a risk-based assessment identified that the change in material of the rollers can affect the useful life of the administration set. The change in the roller material from plastic to stainless steel increases the administration set wear and/or breakage due to fatigue. Evaluation of this risk concluded that the increased fatigue on the administration set is more likely to lead to patient under-dosing before the administration set is intended to be replaced. This significantly changes the device's performance and safety specifications.

Decision: Remanufacturing.

Example E.3

a. Activity: The gradient coil of a magnetic resonance (MR) system was damaged during an imaging session and needs to be replaced. The gradient coil is replaced with a non-OEM gradient coil. The maximum slew rate of the coil matches that of the OEM gradient coil; however, the peak gradient strength is larger than the OEM coil.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. The gradient coil does not have direct or indirect contact with body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The gradient coil was removed and replaced, and the new gradient coil has a larger peak gradient strength.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. An assessment was performed to determine the significance of the change. A gradient coil with a larger peak gradient strength significantly changes the imaging performance specifications (e.g., slice thickness, spatial resolution).

Decision: Remanufacturing.

b. Activity: The gradient coil of an MR system was damaged during an imaging session and needs to be replaced. It is replaced with a non-OEM gradient coil that has different dimensional specifications and coil design.

Relevant questions:
In this example, the answers to flowchart questions A1 and A2 are the same as Example E.3.a. except that for A2, the new gradient coil has different dimensional specifications and coil design.

A2.1 Is there a significant change to device performance or safety specifications?
No. The new gradient coil only differs by small changes in design and dimensional specifications. There are no significant changes to the performance and safety specifications (e.g., slew rate, peak gradient strength, power).

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
No. A risk-based assessment identified no new or modified risks or change in the performance or safety specifications due to this change because the non-OEM gradient coil has the same hardware performance specifications (e.g., slew rate), equivalent imaging performance, and meets the same safety and performance specifications (e.g., acoustic output) when compared to the OEM gradient coil.

Decision: Not Remanufacturing.

Example E.4

Activity: The slide heater pads on an immunohistochemistry (IHC) autostainer are worn out and need to be replaced. They are replaced with an OEM part.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. The slide heater pads do not have direct or indirect contact with body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The heater pad components were physically removed and replaced with new pads.

A2.1 Is there a significant change to device performance or safety specifications?
No. An assessment was performed to evaluate this replacement and identified no changes to dimensions, materials, or performance or safety specifications of the pads.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
No. A risk-based assessment identified no new or modified risks because the slide heater pads are identical to the original part from the OEM. The device now functions within its functional specifications identified in the labeling. There is no change in the performance or safety specifications.

Decision: Not Remanufacturing.

Example E.5

Activity: The tubing on a sample processor became kinked from use and needs to be replaced. Tubing was found from the same OEM, but the tubing is intended for use with a different sample processor.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. There is no direct or indirect contact between the tubing and body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The tubing was removed and replaced with new tubing of a different inner diameter.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. The inner diameter of the tubing is different from the legally marketed device. Verification and validation testing was performed to evaluate this replacement and identified significant changes to performance because different fluid characteristics (e.g., flow rate) than those specified for the legally marketed device were noted with the new tubing.

Decision: Remanufacturing.

Example E.6

Activity: A tissue pre-treatment water bath was updated by replacing the heating chamber with one that has a different temperature range.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. The tissue specimens have been removed from the human body, are within a sealed container, and neither the water bath nor heating chamber directly or indirectly contacts the tissue.

A2 Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The heating chamber was removed and replaced. The heating chamber's performance specifications were changed because the new heating chamber has a different temperature range.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. The performance is significantly changed because the heating range extends beyond that of the heating chamber in the legally marketed device.

Decision: Remanufacturing.

Example E.7

a. **Activity:** A stainless steel manual drill is intended to be used in the implantation of orthopedic devices. The drill is intended to be reprocessed and reused for multiple procedures. The drill was sharpened because it is dull and difficult to use. This is the first time the drill has been sharpened.

   Relevant questions:
   A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
   Yes. Sharpening the drill removes material and exposes a fresh surface that directly contacts bone.

   A1.1 Is there a significant change to device performance or safety specifications?
   No. The drill is not coated. The material and structure of the drill that contacts body tissue is uniform. A risk-based assessment concluded that removal of material due to sharpening as well as the sharpening process itself does not significantly change the biocompatibility or reprocessing.

   A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
   Yes. Sharpening of the drill removes material changing the dimensions of the drill.

   A2.1 Is there a significant change to device performance or safety specifications?
   No. The drill was returned to its performance and safety specifications because the entity sharpened the device to its labeled outer diameter and original edge profile angle.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
Yes. Sharpening the drill may change the size of the resulting pilot drill hole. Changing the size of the pilot hole can change the fit of the implant or overall purchase in bone such that the mechanical integrity of the implant is compromised.

A3.1 Is there a significant change to device performance or safety specifications?
No. Based on the facility's maintenance record, it was determined that this is the first drill sharpening. The drill produces the same pilot hole size as the legally marketed device after the sharpening has been completed. There is no significant change to the device's performance or safety specifications at this time.

Decision: Not Remanufacturing.

b. **Activity:** A stainless steel manual drill with a titanium nitride coating is intended to be used in the implantation of orthopedic devices. The drill is intended to be reprocessed and reused for multiple procedures. The drill was sharpened because it is dull and difficult to use. The drill has been sharpened multiple times.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
Yes. Sharpening the drill removes material and exposes a fresh surface that directly contacts bone.

A1.1 Is there a significant change to device performance or safety specifications?
No. While sharpening the drill exposes the stainless steel surface beneath the coating, both the surface coating and underlying stainless steel have been subjected to a biocompatibility assessment. Additionally, a risk-based assessment concluded that removal of material due to sharpening does not significantly change the biocompatibility or reprocessing.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. Sharpening of the drill removes material changing the dimensions and cutting surface of the drill.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. Based on the facility's maintenance record, it was determined that the drill has been sharpened multiple times. While the outer diameter of the drill is not significantly changed from the legally marketed device, the titanium nitride coating is no longer intact on the cutting surface of the drill, causing inefficient or destructive cutting. This activity significantly changes the device's performance and safety specifications.

Decision: Remanufacturing.

Example E.8

a. **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 (e.g., focal length, Abbe number) and materials as the original lens.

   Relevant questions:
   A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
   Yes, both the lens and the epoxy directly contact body tissue.

   A1.1 Is there a significant change to device performance or safety specifications?
   No. The epoxy is identical to the epoxy used in the legally marketed device. The replacement lens is the same material as original lens. A risk-based assessment that considered both the individual and cumulative changes was performed to determine if the procedure used to replace the lens affects biocompatibility and reprocessing instructions. A biocompatibility assessment confirmed that there are no new surfaces previously unexposed to body tissue. A comprehensive reprocessing risk assessment and testing demonstrated that the validated reprocessing instructions identified in the labeling of the legally marketed device are not impacted by the replacement parts or the procedure used to replace the parts.

   A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
   Yes. The epoxy and lens were replaced.

   A2.1 Is there a significant change to device performance or safety specifications?
   No. The optical performance testing (e.g., resolution and distortion) and reprocessing risk assessment and testing indicated there has been no significant change in performance or safety specifications.

   A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
   No. A risk-based assessment was performed that considered both the individual and cumulative changes that could have affected biocompatibility, reprocessing, and optical performance. This assessment identified that there are no new or modified risks, and there is no change in performance or safety specifications.

   Decision: Not Remanufacturing.

b. **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 (e.g., resolution and

distortion) relative to the original endoscope. The replacement lens has the same material but different optical specifications (e.g., focal length, Abbe number) from the original.

Relevant questions:
In this example, the answers to flowchart questions A1, A1.1, and A2 are the same as Example E.8.a.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. The epoxy is identical to that used in the legally marketed device, but the lens has different optical specifications from the original lens. The endoscope with the replacement lens has different imaging specifications relative to the legally marketed device. While the replacement lens is present on another 510(k)-cleared device, it was not present on the original endoscope and significantly changes the performance specifications of the original endoscope.

Decision: Remanufacturing.

Example E.9

Activity: An endoscope's connection to the video processor was damaged during use. After repair, it was observed that the endoscope readily disconnected from the video processor. To address this problem, an adapter was added to reduce the probability of a disconnection between the endoscope and video processor. The adapter was found to be capable of connecting to the video processor; however, it is bulkier than the connector.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
No. The added adapter does not directly or indirectly contact body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes, the adapter has been added to the endoscope.

A2.1 Is there a significant change to device performance or safety specifications?
No. The adapter still allows the endoscope to be connected to the video processor and optical performance testing demonstrated the same optical performance as the original endoscope.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
Yes. A risk-based assessment was performed to determine the effects of this added component. Increased risks exist with the added adapter, such as disconnection from the light source, and the potential change to the electrical safety and electromagnetic compatibility (EMC) of the device.

A3.1 Is there a significant change to device performance or safety specifications?
Yes. Disconnection from a light source during a procedure could result in a loss of imaging and adverse events such as increased procedure time or other patient injuries such as

perforation. Additionally, testing should also be performed for the electrical safety and EMC of the device.

Decision: Remanufacturing.

Example E.10

Activity: The motor on a powered wheelchair no longer functions and does not propel the wheelchair as intended. The motor was inspected and it was determined that the motor should be replaced. Neither the identical motor nor one with similar specifications could be located. A motor of similar size was inserted with different power and speed specifications.

Relevant questions:

A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?

No. The motor does not directly or indirectly contact body tissue.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

Yes. The original motor was removed and replaced.

A2.1 Is there a significant change to device performance or safety specifications?

Yes. While the motor has the same physical dimensions, the replacement motor has a different power output and maximum speed than the legally marketed device. This significantly changes the device's performance specifications because the wheelchair can go faster than intended. This also significantly changes the device's safety specifications because the controller and software to operate the wheelchair may no longer be compatible with the motor.

Decision: Remanufacturing.

Example E.11

a. **Activity:** The liquid cooling system responsible for maintaining the temperature of a transcranial magnetic stimulation (TMS) coil is malfunctioning and causing the system to overheat. The cooling system was inspected and it was determined that the pump circulating the liquid coolant stopped functioning. A replacement pump was located and installed with no additional changes to the device.

   Relevant questions:

   A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?

   No. The liquid coolant is maintained in the sealed coolant system and neither the liquid coolant nor the pump directly or indirectly contacts body tissue.

   A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?

   Yes, the pump was replaced.

A2.1 Is there a significant change to device performance or safety specifications?
No. Both the dimensions and performance specifications of the original pump were assessed in comparison to the replacement part. The replacement pump has the same dimensional and performance specifications of the original pump. The overall performance and safety specifications of the TMS coils were verified by testing to be the same.

A3. Is there a new or modified risk or is there a change in the performance or safety specifications?
No. A risk-based assessment identified no new or modified risks because the replacement pump is equivalent to that used in the OEM's legally marketed device and there is no change in the device performance or safety specifications.

Decision: Not Remanufacturing.

b. **Activity:** The liquid cooling system responsible for maintaining the temperature of a TMS coil is malfunctioning and causing the system to overheat. The cooling system was inspected and it was determined that the pump circulating the liquid coolant stopped functioning. A replacement pump was located with the same size and flow specifications, but it uses a different coolant liquid. The pump was replaced with one that uses a different coolant into the cooling system.

Relevant questions:
In this example, the answer to flowchart question A1 is the same as Example E.11.a.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. A replacement pump that uses a different coolant liquid was installed.

A2.1 Is there a significant change to device performance or safety specifications?
Yes. Although the pump has the same dimensional and flow specifications as the original pump, the new pump uses a different liquid coolant. The new liquid coolant does not have the same heat capacity as that used in the legally marketed device. Verification and validation testing was performed and it was determined that there was a significant change to cooling effectiveness, which poses a safety hazard when the TMS coil is not properly cooled. This may burn the patient or cause further device malfunctions.

Decision: Remanufacturing.

Example E.12

Activity: An energy-delivering aesthetic device has multiple compatible handpieces with specific areas of application. Applicator A can only be used for the chin, while Applicator B can only be used on the abdomen. An entity cannibalizes Applicator B and uses those parts to repair Applicator A for use on the chin.

Relevant questions:
A1. Add, remove, or change a component/part/material that directly or indirectly contacts body tissue?
Yes. The distal end of Applicator B is used to reconstruct Applicator A. It directly contacts the patient and delivers the energy.

A1.1 Is there a significant change to device performance or safety specifications?
No. The distal end of both applicators has identical materials and the reprocessing instructions provided by the OEM are the same for both applicators. A risk-based assessment was performed to determine the effects of implementing these repairs on the biocompatibility and reprocessing. A biocompatibility assessment and reprocessing risk assessment were used to determine that the performance and safety specifications of the device were not significantly changed.

A2. Add or remove component/part/material or change the dimensional or performance specifications of a component/part/material?
Yes. The distal end of Applicator B has different dimensional specifications compared to Applicator A.

A2.1. Is there a significant change to device performance or safety specifications?
Yes. The surface area that contacts the patient has increased by 150%. The increase in surface area changes the energy output delivered to the patient, which significantly changes both the performance and safety specifications of Applicator A.

Decision: Remanufacturing.

(2) Software activities

Example S.1

Activity: A specular microscope with a camera is intended for examination of corneal endothelium and for measurement of the thickness of the cornea. The software was updated to implement an OEM-authorized patch.

Relevant analysis: The installation of this OEM-authorized patch does not significantly change the device performance or safety specifications. See Section VII of this guidance for further discussion of changes involving software. The patch is intended to maintain the original specifications.

Decision: Not Remanufacturing.

Example S.2

Activity: A device has the capability of real-time remote customer service where the current status of the device can be accessed. A capability is added so that the customer service technician can access and directly manipulate the device, including changing device settings, resetting the device, delivering energy, and positioning the device.

Relevant analysis: The capability of the customer service technician to control the device introduces new risks (e.g., accidental device reset, unintended device movement) and functionality (remote control and access) that significantly changes the finished device's performance and safety specifications.

Decision: Remanufacturing.

Example S.3

Activity: A device that connects to a facility's network has software that was designed to run the Microsoft Windows operating system (OS). Adjustments are made to allow the device to run using a Linux OS.

Relevant analysis: This change introduces new risks and may impact mitigations for existing risks that significantly change the finished device's performance and safety specifications. This is a redesign of the product and includes the addition of integration with both device drivers for the target OS as well as specific features of the OS.

Decision: Remanufacturing.

Appendix B. Documentation Examples

The examples below are to illustrate one possible approach to documentation; other approaches may also be appropriate. Entities are encouraged to use an approach that works for their specific purposes, taking into account the considerations discussed above. Rationale documentation may also be incorporated into existing procedures, forms, and other documents when appropriate. The first example demonstrates a simple change that does not necessitate detailed analysis. The second example demonstrates a more complex change for which additional analysis and reference to supporting documentation are warranted. These are generalized examples to demonstrate documentation principles and do not necessarily account for every possible detail, risk, or consideration.

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

Remanufacturing Assessment
(Example 2)

Product: Endoscope Infinity

UDI:
+H123PARTNO1234567890120/$$420020216LOT123456789012345SXYZ456789012345678/16D20130202C

Date of activities performed: 9/24/2018-9/30/2018

Date assessment completed: 10/1/2018

Description of device: Flexible endoscope

Description of activities performed: Repair device; lens, irrigation channel, and shaft exterior replaced. Each change was individually and cumulatively assessed.

Determination of whether the activity is remanufacturing:
Lens Assessment

- Original lens is cracked and needs replacement; OEM lens and epoxy not available for purchase;
- Equivalent lens with same performance specifications and dimensions used (see biocompatibility assessment (BCA) #EI-001 and Component Comparative Analysis Report (CCAR) #EI-002);
- Epoxy used to secure lens is equivalent to OEM epoxy (see BCA #EI-003 and CCAR #EI-004); and
- Leak, optics, and field of view were verified to be within OEM specifications.

Irrigation Channel Assessment

- Irrigation channel is worn and leaking fluid into the device;
- OEM part available for purchase and used (part #XX44); and
- Irrigation channel installed and checked for leaks and functionality.

Shaft Exterior Assessment

- Shaft exterior damaged during repair activities and needs replacement;
- OEM part not available for purchase; and
- Equivalent shaft exterior with same performance specifications and dimensions used (see BCA #EI-005 and CCAR #EI-006).

Cumulative Change Assessment

- Full device specification list inspected and passed (see Customer Evaluation Report #88239 and OEM specification sheet);
- No change in component exposure to reprocessing when following OEM reprocessing instructions;

- A risk-based assessment was performed in each CCAR report; modified risks were identified with using non-OEM parts but were demonstrated as not significantly changing the device's performance or safety specifications, or intended use; and
- No other change in the risks, or change in the performance or safety specifications, have been identified for the cumulative changes made.

This activity is not remanufacturing.

Reference to related documents supporting the decision-making process:

1. BCA #EI-001
2. CCAR #EI-002
3. BCA #EI-003
4. CCAR #EI-004
5. BCA #EI-005
6. CCAR #EI-006
7. Customer Evaluation Report #88239
8. Endoscope Infinity Specification Sheet

Technician performing service: xxx

Reviewed by: xxx

Signature(s): xxx