

## REMANUFACTURING OR SERVICING OF MEDICAL DEVICES: FDA ISSUES FINAL GUIDANCE PROVIDING ADDITIONAL CLARIFICATION

In May 2024, the U.S. Food and Drug Administration ("FDA") issued a **Final Guidance** titled "Remanufacturing of Medical Devices," clarifying the definition of "remanufacturing" for reusable medical devices in need of maintenance or repair ("Final Guidance"). According to the FDA, the Final Guidance is designed to help medical device servicers understand when certain device repairs and modifications performed on devices "are likely manufacturing," as well as to "provide consistency and better understanding of applicable statutory and regulatory requirements."

The Final Guidance represents the culmination of the FDA's longstanding efforts to provide more guidance on what constitutes remanufacturing versus servicing. In 2018, the agency issued a **report** in response to a request from Congress in the **Food and Drug Administration Reauthorization Act of 2017 (FDARA)**, on "the continued quality, safety, and effectiveness of medical devices with respect to servicing." At the time, the FDA **concluded** that the available evidence "[was] not sufficient to conclude whether or not there is a widespread public health concerns related to the servicing of medical devices, including third-party servicers, that would justify imposing additional/different burdensome regulatory requirements . . ." However, the agency committed to pursue several actions, including clarifying the difference between servicing and remanufacturing. In 2021, the FDA released **draft guidance** aimed at providing clarity on what constitutes remanufacturing and received many comments raising concerns over its focus on the regulation of original equipment manufacturers ("OEMs") rather than the third parties that service medical devices. The Final Guidance aims to address these concerns and offers further clarification on the definitions of remanufacturing and servicing.

Below are some highlights from the Final Guidance.

### REMANUFACTURING VS. SERVICING

In the Final Guidance, the FDA highlights the importance of understanding the distinction between "remanufacturing" and "servicing" and provides updated definitions. "**Remanufacturing**" is defined as "the processing, conditioning, renovating, repackaging, restoring or any other act done to a finished device that significantly changes the finished device's performance, safety specifications or intended use."

"**Servicing**" is defined as "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."

Consistent with previous guidance, the FDA outlines six guiding principles to help determine whether an activity is remanufacturing or servicing:

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

The Final Guidance also includes a flowchart that may help entities determine whether an activity constitutes remanufacturing. However, the FDA notes that the flowchart and accompanying text should not be applied to changes involving software, as many "software changes are likely remanufacturing because of their impact on a product's software architecture, software requirement specifications, unresolved anomalies, and other key characteristics."

The flowchart focuses on the following four main questions:

1. Does the activity involve adding, removing or changing a component/part/material that directly or indirectly contacts patient body tissue?
2. Does the activity involve adding, removing or changing a component/part/material or changing the dimensional or performance specifications of a component/part/material?
3. Does the activity create a new risk or modify existing risk?
4. Does the activity introduce a change in the performance or safety specifications of the device?

The FDA notes that the following types of activities “significantly change the legally marketed device’s performance or safety specification” and are likely remanufacturing and should not be evaluated using the flowchart:

1. Changes to the device’s sterilization methods;
2. Changes to the device’s reprocessing instructions; and
3. Changes to the device’s control mechanism, operating principle or energy type.

## **REGULATORY REQUIREMENTS FOR REMANUFACTURERS**

Remanufacturers are considered “manufacturers” under the Federal Food, Drug and Cosmetic Act (“FD&C Act”) and FDA regulations, and are subject to the same regulatory requirements as the OEMs of the device. Therefore, remanufacturers are expected to comply with establishment registration and listing requirements (21 C.F.R. Part 807), medical device reporting and notifications (21 C.F.R. Parts 803 and 1002), recalls and reports of corrections and removals (21 C.F.R. Parts 7, 806, 810, and 1003), quality system regulation (21 C.F.R. Part 820), and labeling requirements (21 C.F.R. Parts 801, 809, 830, and 1010). The FDA also notes that many device types may require premarket review, including a premarket notification (510(k)) or premarket approval, depending on the device classification. The Final Guidance provides some further considerations for remanufacturers to help comply with these regulatory requirements. The FDA also reminds remanufacturers that they can be subject to investigations and inspections to ensure compliance with the FD&C Act and that the agency has the authority to take enforcement action when needed to achieve compliance.

## **PRACTICAL TAKEAWAYS**

- Any change that significantly impacts the function, purpose or safety specifications of a device is likely to be considered remanufacturing. Servicing activities are mostly focused on maintenance and tend to not impact the device’s original functionality or purpose.
- Companies should follow the guiding principles and flowchart to evaluate whether their activities constitute remanufacturing or servicing. As noted by the FDA, any documentation should be prepared in way that “clearly describes the rationale underlying the conclusion, such as that it can be understood by an FDA investigator or a third party.”
- Remanufacturers are expected to meet the same regulatory requirements as OEMs, including, but not limited to, providing adequate servicing instructions, reporting adverse events, implementing a quality system and submitting premarket notifications.
- Software changes are often considered to be remanufacturing, but activities like implementing updates and upgrades authorized, approved or otherwise provided by the OEM, 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, and turning on or off connectivity features (e.g., Wi-Fi and Bluetooth connectivity) consistent with the OEM’s intended use, are not considered remanufacturing.
- **Appendix A** of the Final Guidance provides illustrative examples of activities along with explanations of why an example is or is not likely to constitute remanufacturing. While each case may be different, these examples provide great insight into how the FDA applies both the guiding principles and the considerations set forth in the accompanying flowchart.

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