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Key Points Related to the FDA's Guidance on Servicing Versus Remanufacturing Medical Devices

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In a recent draft guidance document, the U.S. Food and Drug Administration (the "FDA") outlined principles to help determine whether certain activities constitute "servicing" a medical device or whether they represent "manufacturing."[1] Entities that are "manufacturing" face a wide-array of additional regulatory requirements. Original Equipment Manufacturers ("OEMs") already face many of these requirements, but the guidance document has a number of key points that these manufacturers should consider.

Many medical devices represent equipment or platforms that are reusable and require preventive maintenance and repair during their useful life. The FDA's draft guidance document distinguishes between servicing and remanufacturing. Servicing is maintenance of a distributed, finished device for purposes of returning it to the safety and performance specifications of the OEM to meet its original intended use. Remanufacturing, on the other hand, represents activities done to a finished device that significantly changes the finished device's performance or safety specifications or intended use.

The FDA outlines a number of principles for distinguishing servicing activities from remanufacturing. Using a risk-based approach, these include:

- Assessing whether there is a change to the intended use;
- Determining whether the activities, individually or cumulatively, significantly change the safety or performance specifications of a finished device;
- Evaluating whether any changes require a new marketing submission; and
- Assessing component/part/material dimensional and performance specifications.

First, the FDA's draft guidance document encourages OEMs to provide servicing instructions that facilitate routine maintenance and repair of their reusable devices. To that end, the FDA suggests that the labeling of these devices include the following information, as applicable:

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

This lengthy list could include certain sensitive commercial information. Although the FDA notes that its recommendations are not intended to disclose trade secrets or confidential commercial information, OEM companies will need to carefully consider how they might include sufficiently detailed information without disclosing sensitive commercial data.

Second, OEM customers or third-party service organizations may service the medical device. OEMs may need to caution their customers that the activities of third-party service organizations might result in "remanufacturing," rather than "servicing," and might trigger accompanying regulatory requirements that many service organizations do not currently handle. For example, the draft guidance document notes that, with certain technical exceptions, software changes are likely to be considered remanufacturing because of their impact on a product's software architecture, software requirements specifications, unresolved anomalies, and other key characteristics. OEMs may need to educate their customers about the distinctions that the FDA plans to make between servicing and remanufacturing activities.

Third, although the decision about whether a change to a device triggers the need for a new regulatory submission (such as a new 510(k)) could be independent from the decision about whether such a change constitutes "remanufacturing," the analyses are related. Both analyses evaluate the impact of the change on the intended use and the performance and safety specifications of the device. In its draft guidance document, the FDA has provided a number of examples that illustrate various factors that may be considered in making decisions under either analysis. OEMs may wish to review their change management procedures and training to ensure they appropriately account for such factors in light of this additional guidance.

The FDA is accepting comments from industry and others on the draft guidance document until August 17, 2021.

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[1] FDA Draft Guidance Document: Remanufacturing of Medical Devices (June 24, 2021), available at, https://www.fda.gov/media/150141/download.

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