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NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)
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FDA Seeks Public Comment On Draft Guidance On Remanufacturing Medical Devices

By Mark Durivage, Quality Systems Compliance LLC

On June 24, 2021, the FDA released a draft guidance, Remanufacturing of Medical Devices Draft Guidance for Industry and Food and Drug Administration Staff, for public comment in the Federal Register to help clarify whether repair, servicing, and reprocessing activities performed on devices are likely considered remanufacturing. The clarification is intended to facilitate consistency and better interpretation of applicable statutory and regulatory requirements. The guidance applies to all class I, II, or III reusable medical devices, including software and electronic products. The guidance does not apply to reprocessed single-use devices, regardless of classification. The comment period closes 60 days after the draft guidance was posted on June 24, so the deadline for comments is on or around August 23.

Definitions

The guidance provides definitions to reflect updated understanding and practice:

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. (21 CFR 820.3(w)).

Repair: A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

Reprocessing: 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.

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.

Guiding Principles

The proposed guidance focuses on six fundamental principles to decide if activities meet the definition of remanufacturing:

Principle 1: Assess whether there is a change to the intended use.

Principle 2: Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device.

Principle 3: Evaluate whether any changes to a device require a new marketing submission.

Principle 4: Assess component/part/material dimensional and performance specifications.

Principle 5: Employ a risk-based approach.

Principle 6: Adequately document decision-making.

I'll discuss each principle in more detail below.

Principle 1: Assessing Whether There Is A Change To The Intended Use

The intended use of the device is defined as the general purpose of the device or its function, which encompasses the indications for use (21 CFR 801.4). If the purpose of the servicing activity is to return the device to the safety and performance specifications established by the original equipment manufacturer (OEM) and to meet its original intended use, the activity is not considered remanufacturing. However, if the servicing activity alters the original safety and performance specifications, the activity may be considered remanufacturing and will need a formal evaluation.

Principle 2: Determining Whether The Activities Significantly Change The Safety Or Performance Specifications

Let's revisit the definition of "remanufacture" provided above. Remanufacture "significantly changes" the finished device's performance or safety specifications or intended use. Repair, servicing, and reprocessing activities that are not meant to significantly change the original safety or performance specifications of the device should be evaluated to determine whether they do significantly change the finished device's original safety or performance specifications. Additionally, cumulative changes made during repair, servicing, and reprocessing activities should be evaluated to verify the original safety or performance specifications of the device.

Principle 3: Evaluating Whether Any Changes To A Device Require A New Marketing Submission

21 CFR Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices provides requirements for premarket notification for changes that affect the safety, effectiveness, or intended use of class II medical devices. Therefore, evaluate any repair, servicing, and reprocessing activities to determine whether they do significantly change the finished device's original safety, effectiveness, or intended use and thus require a new 510(k) submission.

Principle 4: Assessing Component/Part/Material Dimensional And Performance Specifications

Repair, servicing, and reprocessing activities that change OEM dimensional and performance specifications, including changes in components, parts, and materials, should be evaluated to verify the original safety or performance specifications of the device. Significant changes may require risk-based verification and validation testing and may require a new 510(k) submission.

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Principle 5: Employing A Risk-Based Approach
The guidance recommends using a risk-based approach, such as ISO 14971: Medical devices – Application of risk management to medical devices, when assessing whether repair, servicing, and reprocessing activities are remanufacturing. Specifically, your risk assessment should evaluate if any new hazards or hazardous situations have been introduced and if any of the known hazards or hazardous situations have changed from the finished device's original (legally marketed) performance or safety specifications or intended use.
Principle 6: Adequately Documenting Decision-Making
The guidance recommends documenting the rationale whether repair, servicing, and reprocessing activities constitute remanufacturing or not. Your rationale should be supported by and include reference to supporting verification and validation data.
Your rationale should specify why the repair, servicing, and reprocessing activities performed on the device do or do not significantly change the safety, performance specifications, or intended use of the legally marketed device. It is appropriate to leverage documentation from previous determinations from the identical activity on the same version or model of a device. The documentation can help support complaints, adverse events, field notifications, and FDA inspections.
Important Considerations & Remanufacturing Determination
In the draft guidance, the FDA states that it 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."
The FDA identifies certain types of activities that the agency believes significantly change the legally marketed device's safety or performance specifications, including changes to the device's sterilization methods, changes to the device's reprocessing instructions, changes to the device's control mechanism, operating principle, or energy type, and intended use.
For repair, servicing, and reprocessing activities that change OEM dimensional and performance specifications, including changes in components, parts, and materials, the guidance provides a flowchart to assist in determining if activities are likely remanufacturing.
The flowchart is intended to be used after an entity determines that there is no significant change to intended use or the device's sterilization methods, reprocessing instructions, control mechanism, operating principle, or energy type. The flowchart does not apply to software. The guidance also emphasizes the flowchart is a visual aid intended to be used in conjunction with the accompanying guiding principles.
As with other guidance documents with flowcharts, such as Deciding When to Submit a 510(k) for a Change to an Existing Device and Deciding When to Submit a 510(k) for a Software Change to an Existing Device, it is a best practice to incorporate the flowchart into your organization's quality management system (QMS).
Conclusion
This proposed guidance will provide industry with clarification on whether repair, servicing, and reprocessing activities performed on devices are likely considered remanufacturing. The flowchart used in conjunction with the six guiding principles will help document and justify the organization's rationale.
Submit written comments before August 23 to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 or electronic comments to https://www.regulations.gov. Please reference docket number FDA-2018-N-3741 and the complete title of the guidance with all comments.

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed and plans to expand as new tools become available.
These tools expand the scope of innovative science-based approaches to help improve the development and assessment of emerging medical technologies. We have provided references for each tool. These tools do not replace FDA-recognized standards or qualified medical device development tools (MDDTs). The FDA has not evaluated the suitability of these tools within any specific context of use.
An essential role of the Office of Science and Engineering Labs is to use the most innovative science to speed medical device development and patient access to safe and effective medical devices by producing tools to help in the assessment of new medical devices.
For more information about the Catalog of Regulatory Science Tools, email OSEL_CDRH@fda.hhs.gov

- **Types of tools:**
- Phantoms
- Methods
- Computational Models and Simulations

Of note from Delphi Consulting Group

1. Should your company have need to make application for Small Business Certification or renew same, send in early, as the FDA is taking a very long time to reply. They are a bit busy.

I2. If you have a list of FDA contacts that is a bit old, you need to update, there have been a large number of changes.
FDA People list

Have a good month, see you next month.

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