FDA Webinar–Remanufacturing of Medical Devices Draft Guidance and Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices Discussion Paper

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The U.S. Food and Drug Administration (FDA) will host a webinar for stakeholders interested in learning more about the remanufacturing draft guidance and the discussion paper on cybersecurity and servicing of medical devices.

This webinar will:

- Help clarify whether activities performed on devices are likely remanufacturing
- Is intended to convey the FDA's current thinking on applicable definitions, and clarify, not change, the regulatory requirements applicable to remanufacturers
- Outline specific cybersecurity challenges and opportunities associated with medical device servicing

Background:

As part of the FDA's ongoing effort to provide consistency and better understanding of applicable statutory and regulatory requirements for medical device remanufacturing and servicing, this webinar is intended to clarify the activities that are likely "remanufacturing" of a device and cybersecurity issues that are unique to the servicing of medical devices.

Register