Due for Service:
FDA's Approach to Medical Device Servicing & Remanufacturing

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Overview

- Medical devices are manufactured by manufacturers, sometimes also called original equipment manufacturers or OEMs
- Medical device manufacturers are required to comply with FDA's Quality System Regulation (QSR), which specifies manufacturing conditions and standards that assure the safety and effectiveness of devices
- Medical devices sometimes need to be serviced to, for example, repair a broken component or update software
- Service can be performed by OEMs or third-parties, sometimes called independent service organizations (ISOs)
- Servicers and the activities they perform are not regulated by FDA
- FDA recently announced a partial solution that relies on clarifying the difference between servicing and remanufacturing

Why is this an issue?

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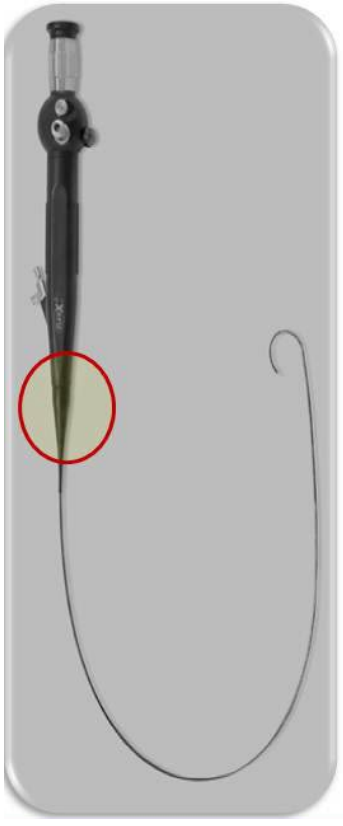

1990s

- October 1996: in announcing the final QSR, FDA noted:

  "Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee…FDA has elected to address application of the cGMP requirements to [servicers and refurbishers] outside the control of the [OEM] in a separate rulemaking later this year…"

- December 1997: FDA asks for public comment on how to apply GMP requirements to refurbishers, "as-is" remarketers, and servicers
- December 1998: FDA no longer applying registration, listing, premarket notification, labeling, and MDR reporting to reconditioners and rebuilders of medical devices

18 years later

2010s

- March 2016: FDA publishes request for comments on possible regulation of third-party servicing, refurbishing, etc. of medical devices
- October 2016: public workshop
- 2017: Congress gets involved
  - Language considered for FDARA would have required registration, quality system, adverse event reporting for servicers
  - Ultimately, Congress requires FDA to issue a report
- May 2018: FDA issues report
- December 2018: public workshop

May 2018 Report: Congressional Mandate

- A description of the statutory and regulatory authority of the Food and Drug Administration with respect to the servicing of devices conducted by any entity, including original equipment manufacturers and third party entities;
- Details regarding how the Food and Drug Administration currently regulates devices with respect to servicing to ensure safety and effectiveness, how the agency could improve such regulation using the authority described in paragraph (3), and whether additional authority is recommended;
- Information on actions the Food and Drug Administration could take under the authority described in paragraphs (3) and (4) to assess the servicing of devices, including the size, scope, location, and composition of third party entities;
- Information on actions the Food and Drug Administration could take to track adverse events caused by servicing errors performed by any entity, including original equipment manufacturers and third party entities;
- Information regarding the regulation by States, the Joint Commission, or other regulatory bodies of device servicing performed by any entity, including original equipment manufacturers and third party entities;

May 2018 Report: FDA Findings

- The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
- Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;
- A majority of comments, complaints, and adverse event reports alleging that inadequate “servicing” caused or contributed to clinical adverse events and deaths actually pertain to “remanufacturing” and not “servicing”; and
- The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.

May 2018 Report: FDA Findings

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December 2018 Public Workshop

- FDA released a white paper to provide specific topics for discussion during the public workshop on device servicing and remanufacturing.
- The white paper identified five guiding principles to determine whether activities are servicing or remanufacturing:
  1. Servicing does not significantly change the safety or performance specifications of a device
  2. Evaluate whether any changes to a device require a new 510(k)
  3. Assess component/part/material dimensional and performance specifications
  4. Employ a risk-based approach
  5. Adequately document decision-making
- FDA also asked for specific feedback on how to handle software and labeling with respect to servicing vs. remanufacturing.

December 2018 Public Workshop

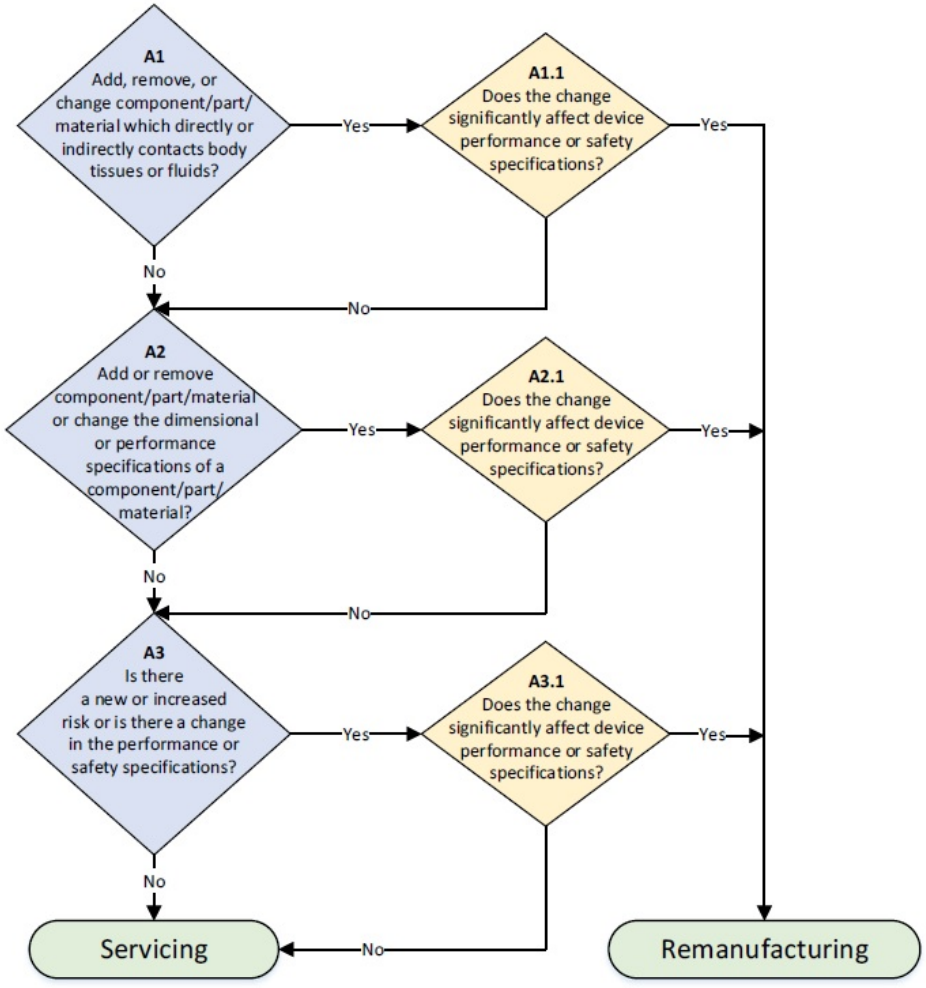


Figure 1. Flowchart proposed to distinguish whether activities performed are servicing or remanufacturing.

December 2018 Public Workshop

- We observed the following areas of agreement among medical device industry stakeholders during the workshop:
  1. Device industry stakeholders generally agree that risk-based assessments are necessary for determining whether an activity is servicing or remanufacturing.
  2. Third-party servicers seemed to acknowledge that establishing a quality system is essential to performing medical device servicing.
  3. Availability of device specifications and documentation is still the most contentious issue.
  4. FDA's flowchart to help differentiate servicing from remanufacturing needs much more detailed decision points.
  5. The draft guidance will not improve patient safety unless FDA is willing to enforce compliance.

December 2018 Public Workshop

- Other conclusions from the public workshop:
  - FDA was very clear that it is trying to avoid formal regulation of third-party servicers.
  - FDA is still seeking collaboration between OEMs and third-party servicers to develop a mutually acceptable solution.
  - OEMs continue to insist upon protection of IP rights, including trade secrets and proprietary documentation and software.
  - Third-party services continue to insist on access to detailed OEM servicing documentation and OEM parts.
  - User facilities are looking for cost effective alternatives to OEM servicing.

Collaborative Community

- A continuing forum in which private- and public-sector members, including the FDA, work together on medical device challenges to achieve common objectives and outcomes.
- Convened by interested stakeholders and may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts.

Conditions for a Collaborative Community

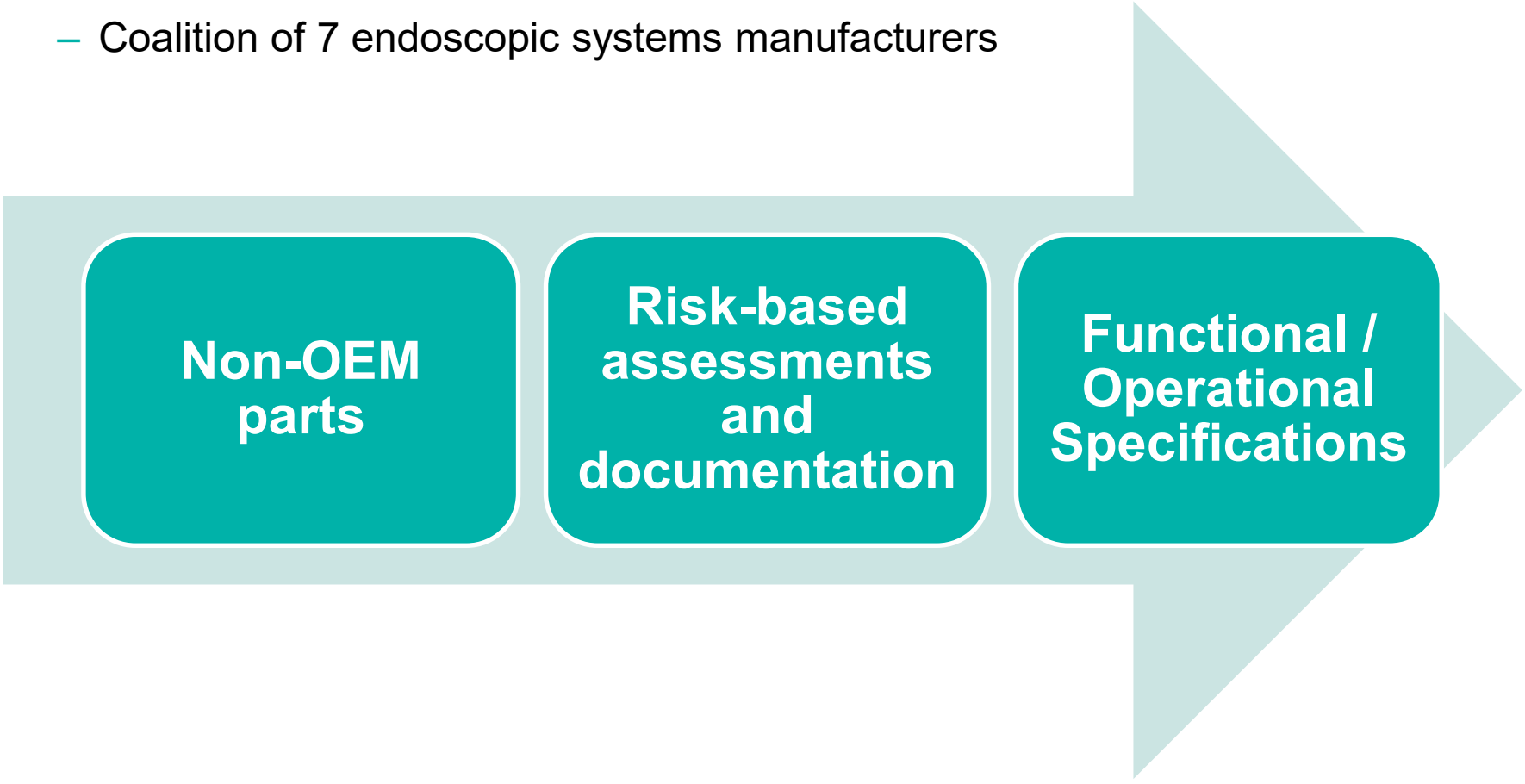
- Challenges are ill-defined or there is no consensus on the definition of the challenges
- Challenges and outcomes are complex
- Partners are interrelated
- Incremental or unilateral efforts to address the challenge have been ineffective
- Partners seek to optimize efforts, including preventing duplication of efforts
- Better outcomes could be achieved with integrating different perspectives, experiences, resources, and expertise

Summary of Comments

- Generally, same old song from both OEMs and third-party servicers
- But, some ideas showed up in comments more than others:
  - Flow chart should be more objective, less subjective
  - Same standards should apply to all servicers (OEMs and third parties)
  - Having OEMs provide some information would be helpful; unclear where to draw the line

Path Forward?

- Two comments aligned more than others
  - Association of Medical Device Service Organizations (AMDSO)
  - Coalition of 7 endoscopic systems manufacturers



Path Forward?

Non-OEM parts	• Parts readily available • Need to match specifications of original
Risk-based assessments and documentation	• More explicit in flow chart • Documentation used by FDA to verify servicing vs. remanufacturing
Functional / Operational Specifications	• Easily determinable/measurable characteristics of a device • So servicer knows they are returning device to original specification

Next Move is FDA's

- FDA reviewing and considering comments
- Draft guidance expected to be issued on or before September 30, 2019
- Don't expect draft guidance to address registration, enforcement

Alternative Models to Solve this Problem

- The typical model of device sales/distribution limits an OEM's control of servicing options.
  - Once a device is sold to a user facility, the rights of the OEM to control that device terminate.
  - In patent law, this is called the "exhaustion doctrine" (or "first sale doctrine").
- BUT, OEMs can alter device design and sales/distribution models to avoid third-party servicing:
  - Offer customers extended warranty periods and reduced cost servicing.
  - Use proprietary fasteners or software security to secure devices and void warranty upon breach.
  - Lease devices rather than sell them.
  - Offer devices and servicing as part of a subscription service.