

Regulation and Supply of Refurbished Medical Devices

FDA Perspective

Lillian Gill, Senior Associate Director
Center for Devices and Radiological Health, FDA
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FDA Regulation of 3 Rs

➤ Reuse

- Single use disposables/devices (SUDs)
- Subject to full regulatory controls

➤ Remanufacturing

- Significant changes to finished device or safety specifications
- Considered a manufacturer; subject to full regulatory controls

FDA Regulation of 3 Rs cont'd

➤ Remarketing

- No significant change to device performance, safety specs, or intended use
- Designed for multiple use
- Primarily capital equipment
- Includes refurbishing, reconditioning, rebuilding, servicing, "as is" sale

Brief Regulatory History

- 1987 Reconditioners, Rebuilders of Medical Devices CPG
- 1996 Quality System Regulation (QSR)
- 1997 FDA request for comments on regulating remarketed devices
- 1999 Joint proposal for alternatives to regulation
- 2000 FDA draft Guidance on Med. Dev. Remarketers and Servicers

QSR Addresses Refurbishers

➤ 1996 QSR

- Initially increased scope to include servicers
- Proposed application of QSR requirements to new and refurbished devices
- Comments provided little evidence of public health problems with refurbished devices
- Planned separate policy for remarketers

Joint Task Group: Alternative Plan

- Response to FDA's 1997 request
- Collaboration of 9 health care organizations
- Voluntary plan vs. FDA regulation
- Applies to all servicing/remarketing
- Hospitals and/or healthcare facilities encouraged to apply

Elements of Voluntary Plan

- Registration - 3rd Party
 - Participant notification of FDA hazard, recall and safety notices
 - Customer notification by participants of same information
- Disclosure of Affiliations
 - Ownership, memberships in trade/professional organizations, ethical codes/stds of practice

Elements of Voluntary Plan cont'd

- Disclosure of certifications, accreditations (e.g., ISO)
- Labeling
 - Name/location of remarketer/servicer
 - Date/nature of work performed
 - Device condition codes
 - DC1 – cosmetic restoration; “as is”/unknown condition
 - DC2 –safe/proper performance; ready for clinical use

Elements of Voluntary Plan cont'd

- Disclosure of all services provided
 - Cleaning
 - Cosmetic restoration
 - Decontamination
 - Installation
 - Performance verification
 - Preventive maintenance
 - Repair
 - Safety testing
- Complaint reporting mechanisms
- Education of users and purchasers

Benefits of Voluntary Program

- Accurate identification of equipment condition / working status
- Understand level of service performed
- Notification of safety alerts, recalls
- Establish better records
- Better inform purchasers
- Less regulatory burden

Status of Program Implementation

- FDA Draft Guidance
 - Clarifies existing requirements for remarketers
 - Subject to general controls e.g., labeling, corrections/removals, performance standards and reports for electronic products
 - Not subject to QSR, Complaints, 510k
 - incorporates principles of voluntary program
- Draft on presently on hold; expected to move forward this later this year

Status of Refurbishers/Serviceers

- Refurbished devices still subject to general controls but not to QSR, registration, clearance
- Voluntary proposal still viable but may change
- Import / Export issues continue