An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals

Website Addresses

- Center for Devices and Radiological Health Home Page
  - http://www.fda.gov/cdrh
- Reuse Home Page
  - http://www.fda.gov/cdrh/reuse/index.shtml
- Registration and Listing Forms for Firms (Registration form only):
  - http://www.fda.gov/cdrh/reglistpage.html (scroll to Downloadable form 2891)
- Classification
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- Examples of Reprocessed Single-Use Devices; Appendix A
  - http://www.fda.gov/cdrh/reuse/1168a.html
- Medical Device Reporting (MDR)
  - http://www.fda.gov/cdrh/mdr.html
- Standards
  - http://www.fda.gov/cdrh/stdsprog.html
- Quality System/Good Manufacturing Practice
  - http://www.fda.gov/cdrh/dsma/cgmphome.html

Documents

- *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA Staff* (8/14/00)
  - http://www.fda.gov/cdrh/comp/guidance/1168.pdf

- *Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff* (6/1/01)
    - http://www.fda.gov/cdrh/ode/guidance/1331.pdf

- *Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA* (7/30/01)
    - http://www.fda.gov/cdrh/comp/guidance/1392.pdf

- *Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use; Final Guidance for Hospital Reprocessors and FDA Staff* (4/24/01)
    - http://www.fda.gov/cdrh/osb/guidance/1334.pdf

- *Frequently Asked Questions about the Reprocessing and Reuse of Single-Use Devices by Third Parties and Hospital Reprocessors; Final Guidance for Industry and FDA Staff* (7/6/01)
    - http://www.fda.gov/cdrh/ohip/guidance/1333.pdf

- *Letter to Hospitals Re: Reprocessing of Single Use Devices* (4/23/01)
    - http://www.fda.gov/cdrh/reuse/042301_reuse.html

- *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance* (4/96)
    - http://www.fda.gov/cdrh/ode/198.pdf

- *Questions & Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities* (9/3/96)
    - http://www.fda.gov/cdrh/ode/1198.html

- *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* (5/1/95)
    - http://www.fda.gov/cdrh/g951.html

- *Use of Standards in Substantial Equivalence Determinations; Guidance for Industry and FDA Staff* (3/12/00)
    - http://www.fda.gov/cdrh/ode/guidance/1131.html

- *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff* (7/20/01)
    - http://www.fda.gov/cdrh/modact/k982.html

- *Frequently Asked Questions on Recognition of Consensus Standards* (6/20/01)
    - http://www.fda.gov/cdrh/ost/guidance/109.html

- *The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* (3/20/98)
    - http://www.fda.gov/cdrh/ode/parad510.html

- *Frequently Asked Questions on the New 510(k) Paradigm; Final Guidance for Industry and FDA* (10/22/98)
    - http://www.fda.gov/cdrh/ode/92_a.html

- *Updated 510(k) Sterility Review Guidance (K90-1), Final Guidance for Industry and FDA* (11/16/01)
    - http://www.fda.gov/cdrh/k90-1.html

- *Guidance on Medical Device Tracking; Guidance for Industry and FDA Staff* (1/24/2000)
    - http://www.fda.gov/cdrh/modact/tracking.pdf

- Compliance Policy Guide (CPG 7124.16) Section 300.500. Reuse of Medical Disposable Devices (9/24/87)
    - http://www.fda.gov/cdrh/comp/cpgreuse.pdf

- *Quality System Regulation - 21 CFR Parts 808, 812, and 820 Medical Devices; Current Good Manufacturing Practice (CGMP); Final Rule*
    - http://www.fda.gov/cdrh/fr1007ap.pdf

- *Guide To Inspections Of Quality Systems* (8/99)
    - http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.pdf

Addresses and Phone Numbers

- Registration and Listing
    - For Questions:
      Division of Small Manufacturers, International & Consumer Assistance (DSMICA)
      1-800-638-2041

    - To request forms and instructions:
      Dsmica@cdrh.fda.gov

    - Address:
      Registration and Listing Branch (HFZ-308)
      Food and Drug Administration (FDA)
      9200 Corporate Blvd.
      Rockville, MD 20850-4015
      Phone: 301-495-7726
      Fax: 301-495-4660

- Coordination of Reuse Policy in Office of Device Evaluation (premarket issues only)

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Barbara Zimmerman	(301) 594-2036
Philip J. Phillips	(301) 594-2022
Heather Rosecrans	(301) 594-1190

- Medical Device Reporting Questions:

  Office of Surveillance and Biometrics
  Food and Drug Administration (FDA)
  Division of Surveillance Systems
  Reporting Systems Monitoring Branch, HFZ-533
  Rockville, MD 20850
  Phone: 301-594-2735
  Fax: 301-827-0038
  E-mail: rsmb@cdrh.fda.gov