CPG Sec. 300.500 *Reprocessing of Single Use* Devices

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This document supersedes Compliance Policy Guide (CPG) "Sec. 300.500 Reuse of Medical Disposable Devices (CPG 7124.16)" that was issued on September 24, 1987.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

Preface

Public Comment:

Written comments regarding this document may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm.

Additional Copies:

A copy of the guidance may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' site includes the guidance and may be accessed at https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm. .

Compliance Policy Guide
Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required.

Sub Chapter 300
General/Processes

Sec. 300.500 *Reprocessing of Single Use* Devices (CPG 7124.16)

BACKGROUND:

*This guidance addresses the practice of reprocessing devices that are labeled or intended for single use. This has become a more prevalent practice in recent years, and the Food and Drug Administration (FDA) has issued multiple guidance documents setting forth its current thinking on the applicability of statutory and regulatory requirements to reprocessed single use devices (SUDs) and the entities that reprocess them. Reprocessing of SUDs was also addressed in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) that amended the Federal Food, Drug, and Cosmetic Act (the Act). MDUFMA established new statutory requirements applicable to reprocessed SUDs, including labeling identifying the devices as reprocessed, submission of validation data for many reprocessed SUDs, and submission of premarket notifications (510(k)s) with validation data for some SUDs that were previously exempt from 510(k) submission requirements.

Some SUDs may not be amenable to reprocessing. Reprocessed SUDs should be capable of withstanding necessary cleaning, disinfection or sterilization, and continue to comply with all applicable FDA requirements after each instance of reprocessing, up to the maximum number of times that the devices are intended by the reprocessors to be reprocessed.

Therefore, the FDA expects that reprocessors of SUDs should be able to demonstrate: (1) that the device can be adequately cleaned and disinfected or sterilized, (2) that the physical characteristics or quality of the device will not be adversely affected by these processes, and (3) that the device continues to comply with applicable FDA requirements.

The following policy does not apply to: (1) health care facilities other than hospitals, (2) permanently implantable pacemakers, (3) hemodialyzers, and (4) "opened-but-unused" SUDs. "Opened-but-unused" devices are defined as single use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but have not been used on a patient and they have not been in contact with blood or bodily fluids. The reuse of permanent pacemakers and hemodialyzers is addressed in Compliance Policy Guide 7124.12 and the Center for Devices and Radiological Health's (CDRH's) "Guidance for Hemodialyzer Reuse Labeling," respectively.

POLICY:

Firms and hospitals that are reprocessing SUDs are considered by FDA to be manufacturers and as such must comply with all of the following statutory and regulatory requirements:

- Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820)
- Medical Device Reporting (Section 519 (a), (b) and (c) of the Act; 21 CFR Part 803)

Manufacturer reporting requirements, and other requirements under this regulation, are more extensive than device user facility requirements. Hospitals that engage in manufacturing activities, such as reprocessing, are subject to manufacturer reporting requirements (21 CFR Part 803, Subpart E) as

well as user facility reporting requirements (21 CFR Part 803, Subpart C) for the SUDs that they reprocess. Additionally, they must adhere to user facility reporting requirements for all other medical devices that they use.

- Registration and Listing (Section 510 of the Act; 21 CFR Part 807)
- Labeling (Section 502 of the Act; 21 CFR Part 801)

In addition to generally applicable labeling requirements, MDUFMA added a new labeling requirement for reprocessed SUDs (Section 502(v) of the Act). Reprocessed SUDs that are introduced into interstate commerce after January 26, 2004 must prominently and conspicuously bear the statement "Reprocessed device for single use. Reprocessed by [insert the name of the manufacturer that reprocessed the device]."

- Premarket Approval and Premarket Notification (510(k)) (Sections 510, 513 and 515 of the Act; 21 CFR Part 807 and 21 CFR Part 814)

Under MDUFMA, reprocessors of some SUDs that were previously exempt under Sections 510(l) or (m) of the Act from 510(k) submission requirements are no longer exempt and are required under Section 510(o)(2) of the Act to submit 510(k)s that include validation data. Validation data was also required for some reprocessed SUDs that already had cleared 510(k)s. Under Section 510(o) of the Act, reprocessors that either did not submit validation data for those reprocessed SUDs within specified timeframes or received not substantially equivalent letters from FDA can no longer legally market those reprocessed devices. Finally, under Section 515(c)(2) of the Act, reprocessors of Class III SUDs are required to submit premarket reports instead of premarket approval applications.

- Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806)
- Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821)

Manufacturers are not subject to the Medical Device Tracking Regulation unless and until FDA issues a direct order to the manufacturer requiring tracking of a device. Accordingly, a SUD reprocessor will not be subject to the Tracking Regulation unless FDA issues an order to the firm requiring tracking of the specific device(s) being reprocessed.

REGULATORY ACTION GUIDANCE:

If significant violations are observed, a Warning Letter and appropriate regulatory action should be considered. Warning Letters should have concurrence from CDRH's Office of Compliance before being issued.*

* Material between asterisks is new or revised.*

Issued: 11/11/77

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