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# Regulatory Panel

Susan Runner, DDS, MA  
Dental Devices Branch Chief  
FDA

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## Content

- Reuse/single use
- Reprocessing
- Multi-dose dispensers
- FDA/EPA

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Reuse



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## Instructions for Reprocessing

- Incumbent on manufacturer to provide:
  - validated cleaning and sterilization instructions



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# Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

## Guidance for Industry and Food and Drug Administration Staff

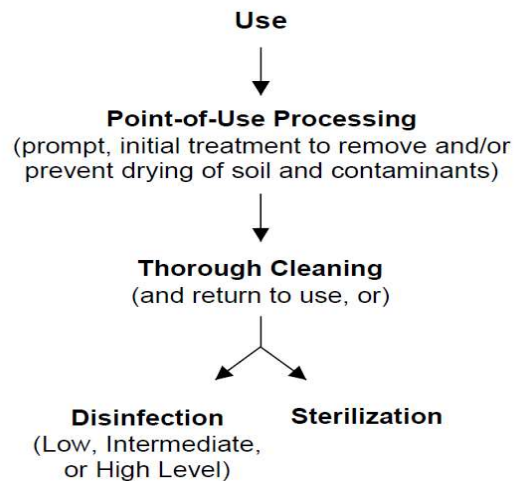
Document issued on: March 17, 2015

- [http://www.fda.gov/downloads/Medical Devices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf](http://www.fda.gov/downloads/Medical%20Devices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf)

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**FIGURE 1. PROCESS OVERVIEW**



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## FDA's Six Criteria for Reprocessing Instructions

- Account for Intended use
- Cleaning
- Appropriate microbicidal process
- Technically feasible
- Comprehensive
- Understandable

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## Can this be adequately reprocessed?




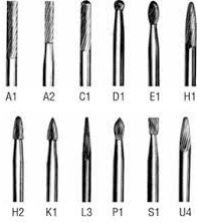
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## Single Use Devices

- no reprocessing instructions
  - considered single use

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## Restorative Materials

- Multi-use dispensers
  - (formerly syringes)
    - Not able to sterilize
    - Appropriate infection control??



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## FDA/EPA

- High Level Disinfectants/Liquid Chemical Sterilants
  - regulation

