FDA Regulations and Infection Control in the Dental Setting

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Regulatory 101

Classification
Exemption
Instructions for use
Classification of Devices

• Class I, II and III
Examples
Examples
Exemptions

- Class I
- Class II

- Not exempt from FDA labeling requirements
Instructions for Use

• 21 CFR PART 801- Labeling

• Adequate directions for use
Reprocessing Medical Devices

• Adequate directions for use include instructions on preparing a device for initial use and reuse
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

**FIGURE 1. PROCESS OVERVIEW**

Use

↓

Point-of-Use Processing
(prompt, initial treatment to remove and/or prevent drying of soil and contaminants)

↓

Thorough Cleaning
(and return to use, or)

↓

Disinfection  Sterilization
(Low, Intermediate, or High Level)
FDA’s Six Criteria for Reprocessing Instructions

» Design of Device
» Human Factors
» Validation
Validation Reprocessing Instructions

• Must establish and maintain procedures
• Monitor and Control process parameters

• Note Exemption from 510(k) does not mean a device is exempt from labeling or quality system requirements
ANSI/AAMI ST 79

• FDA Use of this Standard
• What we ask of a manufacturer
  • Cleaning, Time, Temp, dry time with FDA cleared sterilizer and BI’s and CI’s
Specific Issues of Concern

- Scanner Wand for optical impression systems
- Anesthetic carpule
- Barrier sheaths
- Diamond Burs, other burs and endodontic files
- Multi-use dispensers
Multi-Use Dental Dispenser

Known as Multi-dose syringes

The FDA and CDC prefer the term “Multi-use dispenser”

Dispenser use options:

Single-Use disposable dispenser

Single-Use disposable tips with:

Barrier protection on entire dispenser

Dispensed by assistant in dappen Dish

Sterilizable dispenser
Multi- Use Dispensers

• http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm
Useful FDA Information for Device Selection

• FDA 510(k) Database

• FDA Registration Database
Using FDA 510(k) Database

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Applicant</th>
<th>510(k) Number</th>
<th>Decision Date</th>
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<tbody>
<tr>
<td>Smartburs</td>
<td>S.S. White Burs, Inc.</td>
<td>K000007</td>
<td>06/20/2008</td>
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<tr>
<td>Bti Sterile Dental Drill Kit, Bti Abutm</td>
<td>B.T.I. Biotechnology Institute, S.L.</td>
<td>K081383</td>
<td>08/03/2006</td>
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<tr>
<td>Tri Hawk Bur, Fg Bur</td>
<td>Tri Hawk Corp.</td>
<td>K043273</td>
<td>08/01/1994</td>
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<td>Monosteryl</td>
<td>Utensili Super Abrasivi</td>
<td>K026205</td>
<td>02/10/1994</td>
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<tr>
<td>Dental Or Surgical Bur</td>
<td>Stratum Dental Technologies, Inc.</td>
<td>K023883</td>
<td>07/27/1993</td>
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<tr>
<td>Silicon Bur Block</td>
<td>Innovators, Inc.</td>
<td>K021406</td>
<td>04/28/1992</td>
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<td>Smart Burs Total Carbides</td>
<td>Vermont Diamond Instruments</td>
<td>K020243</td>
<td>03/25/1992</td>
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<tr>
<td>Tin Coated Dental Burs</td>
<td>Surgical Precision Instruments, Corp.</td>
<td>K911208</td>
<td>09/16/1991</td>
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</tbody>
</table>
Device Registration Database

Establishment Registration & Device Listing

This database includes:
- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.
Learn More...

Search Database

Establishment Name
Owner/Operator Name
Proprietary Name
Product Code
Establishment State (U.S.)
Registration Number
Owner/Operator Number
Classification
Device Name
Establishment Type
Establishment Country

Other Databases
- 510(k)
- Adverse Events (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

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