

§ 872.1

21 CFR Ch. I (4–1–08 Edition)

- 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
- 872.5580 Oral rinse to reduce the adhesion of dental plaque.

Subpart G—Miscellaneous Devices

- 872.6010 Abrasive device and accessories.
- 872.6030 Oral cavity abrasive polishing agent.
- 872.6050 Saliva absorber.
- 872.6070 Ultraviolet activator for polymerization.
- 872.6080 Airbrush.
- 872.6100 Anesthetic warmer.
- 872.6140 Articulation paper.
- 872.6200 Base plate shellac.
- 872.6250 Dental chair and accessories.
- 872.6290 Prophylaxis cup.
- 872.6300 Rubber dam and accessories.
- 872.6350 Ultraviolet detector.
- 872.6390 Dental floss.
- 872.6475 Heat source for bleaching teeth.
- 872.6510 Oral irrigation unit.
- 872.6570 Impression tube.
- 872.6640 Dental operative unit and accessories.
- 872.6650 Massaging pick or tip for oral hygiene.
- 872.6660 Procelain powder for clinical use.
- 872.6670 Silicate protector.
- 872.6710 Boiling water sterilizer.
- 872.6730 Endodontic dry heat sterilizer.
- 872.6770 Cartridge syringe.
- 872.6855 Manual toothbrush.
- 872.6865 Powered toothbrush.
- 872.6870 Disposable fluoride tray.
- 872.6880 Preformed impression tray.
- 872.6890 Intraoral dental wax.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 30097, Aug. 12, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 872.1 Scope.

(a) This part sets forth the classification of dental devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the de-

vice is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a dental device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh.guidance.html>.

[52 FR 30097, Aug. 12, 1987, as amended at 68 FR 19737, Apr. 22, 2003]

§ 872.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device