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(iii) Testing to demonstrate compatibility with the indicated external controller.
(iv) Shelf life testing.

(3) Animal testing must demonstrate that the device does not cause esophageal injury and that body temperature remains within appropriate boundaries under anticipated conditions of use.

(4) Labeling must include the following:
(i) Detailed insertion instructions.
(ii) Warning against attaching the device to unintended connections, such as external controllers for which the device is not indicated, or pressurized air outlets instead of vacuum outlets for those devices, including gastric suction.
(iii) The operating parameters, name, and model number of the indicated external controller.
(iv) The intended duration of use.

[80 FR 49896, Aug. 18, 2015]

§ 870.5925 Automatic rotating tourniquet.

(a) Identification. An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

(b) Classification. Class II (performance standards).

PART 872—DENTAL DEVICES

Subpart A—General Provisions

Sec.
872.1 Scope.
872.3 Effective dates of requirement for premarket approval.
872.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

872.1500 Gingival fluid measurer.
872.1720 Pulp tester.
872.1730 Electrode gel for pulp testers.
872.1740 Caries detection device.
872.1745 Laser fluorescence caries detection device.
872.1800 Extraoral source x-ray system.
872.1810 Intraoral source x-ray system.
872.1820 Dental x-ray exposure alignment device.
872.1850 Dental x-ray position indicating device.
872.1850 Lead-lined position indicator.
872.1870 Sulfide detection device.
872.1905 Dental x-ray film holder.
872.2050 Dental sonography device.
872.2060 Jaw tracking device.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

872.3060 Noble metal alloy.
872.3070 Dental amalgam, mercury, and amalgam alloy.
872.3080 Mercury and alloy dispenser.
872.3100 Dental amalgamator.
872.3110 Dental amalgam capsule.
872.3130 Preformed anchor.
872.3140 Resin applicator.
872.3150 Articulator.
872.3165 Precision attachment.
872.3220 Facebow.
872.3240 Dental bur.
872.3250 Calcium hydroxide cavity liner.
872.3260 Cavity varnish.
872.3275 Dental cement.
872.3285 Preformed clasp.
872.3300 Hydrophilic resin coating for dentures.
872.3310 Coating material for resin fillings.
872.3330 Preformed crown.
872.3350 Gold or stainless steel cusp.
872.3360 Preformed cusp.
872.3400 Karaya and sodium borate with or without acacia denture adhesive.
872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.
872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.
872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive.
872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.
872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylenelether maleic acid calcium-sodium double salt denture adhesive.
872.3500 Polyvinylmethylenelether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.
872.3520 OTC denture cleanser.
872.3530 Mechanical denture cleaner.
872.3540 OTC denture cushion or pad.
872.3560 OTC denture reliner.
872.3570 OTC denture repair kit.
872.3580 Preformed gold denture tooth.
872.3590 Preformed plastic denture tooth.
872.3600 Partially fabricated denture kit.
872.3630 Endosseous dental implant abutment.
872.3640 Endosseous dental implant.
872.3645 Subperiosteal implant material.
Food and Drug Administration, HHS

§ 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

Subpart A—General Provisions

872.3660 Impression material.
872.3661 Optical Impression Systems for CAD/CAM.
872.3670 Resin impression tray material.
872.3680 Polytetrafluoroethylene (PTFE) vitreous carbon materials.
872.3690 Tooth shade resin material.
872.3710 Base metal alloy.
872.3730 Pantograph.
872.3740 Retentive and splinting pin.
872.3750 Bracket adhesive resin and tooth conditioner.
872.3760 Denture relining, repairing, or rebasing resin.
872.3765 Pit and fissure sealant and conditioner.
872.3770 Temporary crown and bridge resin.
872.3810 Root canal post.
872.3820 Endodontic paper point.
872.3830 Endodontic silver point.
872.3840 Endodontic stabilizing splint.
872.3850 Endodontic stabilizing splint.
872.3890 Endodontic stabilizing splint.
872.3900 Posterior artificial tooth with a metal insert.
872.3910 Backing and facing for an artificial tooth.
872.3920 Porcelain tooth.
872.3930 Bone grafting material.
872.3940 Total temporomandibular joint prosthesis.
872.3950 Glenoid fossa prosthesis.
872.3960 Mandibular condyle prosthesis.
872.3970 Interarticular disc prosthesis.
872.3980 Endosseous dental implant accessories.

Subpart B—Surgical Devices

872.4110 Bone cutting instrument and accessories.
872.4120 Intraoral dental drill.
872.4130 Dental handpiece and accessories.
872.4140 Gas-powered jet injector.
872.4150 Spring-powered jet injector.
872.4160 Endodontic diamond instrument.
872.4170 Dental hand instrument.
872.4180 Intracutaneous ligature and wire lock.
872.4190 Fiber optic dental light.
872.4200 Dental operating light.
872.4210 Dental injecting needle.
872.4220 Bone plate.
872.4230 Temporary mandibular condyle reconstruction plate.
872.4240 Rotary scaler.
872.4250 Ultrasonic scaler.
872.4260 Intraosseous fixation screw or wire.
872.4270 Dental electrosurgical unit and accessories.

Subpart C—Therapeutic Devices

872.5410 Orthodontic appliance and accessories.
872.5420 Orthodontic plastic bracket.
872.5430 Extraoral orthodontic headgear.
872.5440 Orthodontic appliance and accessories.
872.5450 Orthodontic plastic bracket.
872.5500 Preformed orthodontic headgear.
872.5550 Teething ring.
872.5560 Electrical salivary stimulatory system.
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 D—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 Oral irrigation unit.
872.6410 Impression tube.
872.6420 Dental operative unit and accessories.
872.6460 Dental operative unit and accessories.
872.6470 Heat source for bleaching teeth.
872.6510 Dental electrosurgical unit and accessories.
872.6560 Porcelain powder for clinical use.
872.6570 Silicate protector.
872.6580 Intraoral devices for snoring and obstructive sleep apnea.
872.6590 Oral rinse to reduce the adhesion of dental plaque.
872.6650 Massaging pick or tip for oral hygiene.
872.6660 Porcelain powder for clinical use.
872.6670 Silicate protector.
872.6710 Boiling water sterilizer.
872.6720 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.

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

Editorial Note: Nomenclature changes to part 872 appear at 73 FR 35311, June 23, 2008.