

normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Classification.* Class II (performance standards).

(b) *High-energy DC-defibrillator—(1) Identification.* A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a DC-defibrillator (including paddles) described in paragraph (b)(1) of this section that was in commercial distribution before May 28, 1976. Any other DC-defibrillator (including paddles) described in paragraph (b)(1) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.5325 Defibrillator tester.

(a) *Identification.* A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

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

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) *Identification.* An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987]

§ 870.5800 Compressible limb sleeve.

(a) *Identification.* A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

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

§ 870.5900 Thermal regulating system.

(a) *Identification.* A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

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

§ 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 pre-market 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.

872.1800 Extraoral source x-ray system.

872.1810 Intraoral source x-ray system.

872.1820 Dental x-ray exposure alignment device.

872.1830 Cephalometer.

872.1840 Dental x-ray position indicating device.

872.1850 Lead-lined position indicator.

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Subpart C [Reserved]

Subpart D—Prosthetic Devices

872.3050 Amalgam alloy.

872.3060 Gold based alloys and precious metal alloys for clinical use.

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.

872.3200 Resin tooth bonding agent.

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 polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

872.3500 Polyvinylmethylether 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.

872.3640 Endosseous implant.

872.3645 Subperiosteal implant material.

872.3660 Impression material.

872.3670 Resin impression tray material.

872.3680 Polytetrafluoroethylene (PTFE) vitreous carbon material.

872.3690 Tooth shade resin material.

872.3700 Dental mercury.

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 re-basing resin.

872.3765 Pit and fissure sealant and conditioner.

872.3770 Temporary crown and bridge resin.

872.3810 Root canal post.

872.3820 Root canal filling resin.

872.3830 Endodontic paper point.

872.3840 Endodontic silver point.

872.3850 Gutta percha.

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 Tricalcium phosphate granules for dental bone repair.

872.3940 Total temporomandibular joint prosthesis.

872.3950 Glenoid fossa prosthesis.

872.3960 Mandibular condyle prosthesis.

872.3970 Interarticular disc prosthesis (interpositional implant).

Subpart E—Surgical Devices

872.4120 Bone cutting instrument and accessories.

872.4130 Intraoral dental drill.

872.4200 Dental handpiece and accessories.