§ 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 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.
872.1520 Pulp tester.
872.1720 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.
872.1830 Cephalometer.
872.1840 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.

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872.3110 Dental amalgam capsule.
872.3130 Preformed anchor.
872.3140 Resin applicator.
872.3150 Articulator.
872.3165 Precision attachment.
872.3220 Resin tooth bonding agent.
872.3225 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.
872.3380 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 polyvinylmethylene 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 OTC denture cushion or pad.
872.3535 OTC denture reliner.
872.3550 OTC denture repair kit.
872.3555 Preformed gold denture tooth.
872.3560 Partially fabricated denture kit.
872.3565 Endosseous dental implant abutment.
872.3570 Endosseous dental implant.
872.3575 Subperiosteal implant material.
872.3580 Impression material.
872.3590 Optical Impression Systems for CAD/CAM.
872.3600 Resin impression tray material.
872.3620 Polytetrafluoroethylene (PTFE) vitreous carbon materials.
872.3630 Tooth shade resin material.
872.3640 Base metal alloy.
872.3650 Pantograph.
872.3660 Bracket adhesive resin and tooth conditioner.
872.3670 Denture relining, repairing, or rebasing resin.
872.3680 Pin and fissure sealant and conditioner.
872.3690 Temporary crown and bridge resin.