

§ 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.
872.1745 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.

- 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.
872.3630 Endosseous dental implant abutment.
872.3640 Endosseous dental implant.
872.3645 Subperiosteal implant material.
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.
872.3700 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.