§ 870.5550

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 II. The special controls for this device are:

1. ‘‘American National Standards Institute/American Association for Medical Instrumentation’s DF–21 ‘Cardiac Defibrillator Devices’ ’’ 2d ed., 1996, and

2. ‘‘The maximum pulse amplitude should not exceed 200 milliamperes. The maximum pulse duration should not exceed 50 milliseconds.’’


§ 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 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.

872.1830 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.