counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before March 31, 2014, been found to be substantially equivalent to any external counter-pulsating device, with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other external counter-pulsating device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[78 FR 79307, Dec. 30, 2013]

§ 870.5300 DC-defibrillator (including paddles).

(a) Low-energy DC-defibrillator—(1) Identification. A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring 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. 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.


§ 870.5310 Automated external defibrillator.

(a) Identification. An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. An AED analyzes the patient’s electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) Classification. Class III (premarket approval)

(c) Date PMA or notice of PDP is required. No effective date has been established of the requirement for premarket approval. See §870.3.

[68 FR 61344, Oct. 28, 2003; 69 FR 10615, Mar. 8, 2004]

§ 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 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.
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872.3110 Dental amalgam capsule.
872.3130 Preformed anchor.
872.3140 Resin applicator.
872.3150 Articulator.
872.3165 Precision attachment.
872.3200 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.