Food and Drug Administration, HHS

§ 870.4875 Intraluminal artery stripper.
(a) Identification. An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)
(b) Classification. Class II (performance standards).

§ 870.4885 External vein stripper.
(a) Identification. An external vein stripper is an extravascular device used to remove a section of a vein.
(b) Classification. Class II (performance standards).

Subpart F—Cardiovascular Therapeutic Devices

§ 870.5050 Patient care suction apparatus.
(a) Identification. A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.
(b) Classification. Class II (performance standards).

§ 870.5150 Embolectomy catheter.
(a) Identification. An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.
(b) Classification. Class II (performance standards).

§ 870.5175 Septostomy catheter.
(a) Identification. A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of certain infants.
(b) Classification. Class II (performance standards).

§ 870.5200 External cardiac compressor.
(a) Identification. An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.
(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. See §870.3.

§ 870.5225 External counter-pulsating device.
(a) Identification. An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body’s limbs in synchrony with the heart cycle.
(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. See §870.3.

§ 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
§ 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 II (performance standards).

§ 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).