

Food and Drug Administration, HHS

§ 870.1

870.3670 Pacemaker charger.
870.3680 Cardiovascular permanent or temporary pacemaker electrode.
870.3690 Pacemaker test magnet.
870.3700 Pacemaker programmers.
870.3710 Pacemaker repair or replacement material.
870.3720 Pacemaker electrode function tester.
870.3730 Pacemaker service tools.
870.3800 Annuloplasty ring.
870.3850 Carotid sinus nerve stimulator.
870.3925 Replacement heart valve.
870.3935 Prosthetic heart valve holder.
870.3945 Prosthetic heart valve sizer.

Subpart E—Cardiovascular Surgical Devices

870.4075 Endomyocardial biopsy device.
870.4200 Cardiopulmonary bypass accessory equipment.
870.4205 Cardiopulmonary bypass bubble detector.
870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.
870.4220 Cardiopulmonary bypass heart-lung machine console.
870.4230 Cardiopulmonary bypass defoamer.
870.4240 Cardiopulmonary bypass heat exchanger.
870.4250 Cardiopulmonary bypass temperature controller.
870.4260 Cardiopulmonary bypass arterial line blood filter.
870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter.
870.4280 Cardiopulmonary prebypass filter.
870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.
870.4300 Cardiopulmonary bypass gas control unit.
870.4310 Cardiopulmonary bypass coronary pressure gauge.
870.4320 Cardiopulmonary bypass pulsatile flow generator.
870.4330 Cardiopulmonary bypass on-line blood gas monitor.
870.4340 Cardiopulmonary bypass level sensing monitor and/or control.
870.4350 Cardiopulmonary bypass oxygenator.
870.4360 Nonroller-type cardiopulmonary bypass blood pump.
870.4370 Roller-type cardiopulmonary bypass blood pump.
870.4380 Cardiopulmonary bypass pump speed control.
870.4390 Cardiopulmonary bypass pump tubing.
870.4400 Cardiopulmonary bypass blood reservoir.
870.4410 Cardiopulmonary bypass in-line blood gas sensor.
870.4420 Cardiopulmonary bypass cardiotomy return sucker.

870.4430 Cardiopulmonary bypass intracardiac suction control.
870.4450 Vascular clamp.
870.4475 Surgical vessel dilator.
870.4500 Cardiovascular surgical instruments.
870.4875 Intraluminal artery stripper.
870.4885 External vein stripper.

Subpart F—Cardiovascular Therapeutic Devices

870.5050 Patient care suction apparatus.
870.5150 Embolectomy catheter.
870.5175 Septostomy catheter.
870.5200 External cardiac compressor.
870.5225 External counter-pulsating device.
870.5300 DC-defibrillator (including paddles).
870.5325 Defibrillator tester.
870.5550 External transcutaneous cardiac pacemaker (noninvasive).
870.5800 Compressible limb sleeve.
870.5900 Thermal regulating system.
870.5925 Automatic rotating tourniquet.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 7907-7971, Feb. 5, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17735, May 11, 1987]