§ 870.3545 Ventricular bypass (assist) device.

(a) Identification. A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976. Any other ventricular bypass (assist) device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 870.3600 External pacemaker pulse generator.

(a) Identification. An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart’s intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 870.3610 Implantable pacemaker pulse generator.

(a) Identification. An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart’s intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.


§ 870.3620 Pacemaker lead adaptor.

(a) Identification. A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions.”


§ 870.3630 Pacemaker generator function analyzer.

(a) Identification. A pacemaker generator function analyzer is a device that
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§ 870.3640 Indirect pacemaker generator function analyzer.

(a) Identification. An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient’s skin.

(b) Classification. Class II (performance standards).

§ 870.3650 Pacemaker polymeric mesh bag.

(a) Identification. A pacemaker polymeric mesh bag is an implanted device used to hold a pacemaker pulse generator. The bag is designed to create a stable implant environment for the pulse generator.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §870.9.

§ 870.3670 Pacemaker charger.

(a) Identification. A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §870.9.

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

(a) Temporary pacemaker electrode—(1) Identification. A temporary pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an external pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) Classification. Class III (premarket approval).

(b) Permanent pacemaker electrode—(1) Identification. A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 4, 2012, for any permanent pacemaker electrode device that was in commercial distribution before May 28, 1976, or that has, on or before October 4, 2012, been found to be substantially equivalent to any permanent pacemaker electrode device that was in commercial distribution before May 28, 1976. Any other pacemaker repair or replacement material device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 870.3690 Pacemaker test magnet.

(a) Identification. A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in