

Food and Drug Administration, HHS

§ 870.3690

entitled "Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.3630 Pacemaker generator function analyzer.

(a) *Identification.* A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

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

§ 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.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 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.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 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 II (performance standards).

(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 a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 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