Food and Drug Administration, HHS

§ 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 subpart E of part 807 of this chapter.

§ 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.

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

§ 870.3660 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.

§ 870.3670 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.

§ 870.3640 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).

§ 870.3620 Pacemaker test magnet.

(a) Identification. A pacemaker test magnet is a device used 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).

§ 870.3690 Pacemaker test magnet.

(a) Identification. A pacemaker test magnet is a device used 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.

§ 870.3660 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.

§ 870.3670 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.

§ 870.3680 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.

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

§ 870.3660 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.

§ 870.3670 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.

§ 870.3680 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.

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