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.

(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 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 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 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.