Food and Drug Administration, HHS

§ 870.3730 Pacemaker repair or replacement material.

(a) Identification. A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(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 pacemaker repair or replacement material 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 pacemaker repair or replacement material 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.

§ 870.3710 Pacemaker repair or replacement material.

(a) Identification. A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(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 pacemaker repair or replacement material 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 pacemaker repair or replacement material 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.

§ 870.3720 Pacemaker electrode function tester.

(a) Identification. A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient’s pacing threshold and intracardiac R-wave potential.

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

§ 870.3730 Pacemaker service tools.

(a) Identification. Pacemaker service tools are devices such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker 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.