§ 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 device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

§ 870.3630 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.
Food and Drug Administration, HHS § 870.3730

§ 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.