§ 870.3700 Pacemaker programmers.

(a) Identification. A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

(b) 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. See §870.3.

§ 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 a PDP is required. No effective date has been established of the requirement for premarket approval. See §870.3.

§ 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.
natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) **Classification.** Class III (premarket approval).

(c) **Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 9, 1987 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has on or before December 9, 1987 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 870.3935 Prosthetic heart valve holder.

(a) **Identification.** A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) **Classification.** Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§ 870.3945 Prosthetic heart valve sizer.

(a) **Identification.** A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(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.

[65 FR 19319, Apr. 11, 2000]

§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) **Identification.** A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

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