

**§ 870.3470**

**21 CFR Ch. I (4–1–10 Edition)**

**§ 870.3470 Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.**

(a) *Identification.* An intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

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

**§ 870.3535 Intra-aortic balloon and control system**

(a) *Identification.* A intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

(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.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

**§ 870.3545 Ventricular bypass (assist) device.**

(a) *Identification.* A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.

(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.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

**§ 870.3600 External pacemaker pulse generator.**

(a) *Identification.* An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(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.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

**§ 870.3610 Implantable pacemaker pulse generator.**

(a) *Identification.* An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device includes triggered, inhibited, and asynchronous devices implanted in the human body.

(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.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

**§ 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 special control for this device is the FDA guidance document