

(2) Sterility and shelf life testing should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(3) Non-clinical and clinical performance testing should demonstrate substantial equivalence in safety and effectiveness, including durability, compatibility, migration resistance, corrosion resistance, and delivery and deployment;

(4) Non-clinical testing should evaluate the compatibility of the device in an magnetic resonance (MR) environment;

(5) Appropriate analysis and non-clinical testing should validate electromagnetic compatibility (EMC) and electrical safety;

(6) The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109 of this chapter; and

(7) Labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the non-clinical and clinical evaluations pertinent to use of the device.

[77 FR 8119, Feb. 14, 2012]

**§ 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.* An intra-aortic balloon and control system is a prescription 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.* (1) Class II (special controls) when the device is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure. The special controls for this device are:

(i) Appropriate analysis and non-clinical testing must be conducted to validate electromagnetic compatibility and electrical safety of the device;

(ii) Software verification, validation, and hazard analysis must be performed;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility and shelf-life testing must demonstrate the sterility of patient-contacting components and the shelf life of these components;

(v) Non-clinical performance evaluation of the device must demonstrate mechanical integrity, durability, and reliability to support its intended purpose; and

(vi) Labeling must include a detailed summary of the device- and procedure-related complications pertinent to use of the device.

(2) Class III (premarket approval) when the device is indicated for septic shock and pulsatile flow generation.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (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 March 31, 2014, for any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976, or that has, on or before March 31, 2014, been found to be substantially equivalent to any intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation that was in commercial distribution before May 28, 1976. Any other intra-aortic balloon and control system indicated for septic shock or pulsatile flow generation shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[78 FR 79303, Dec. 31, 2013]