Subpart D—Cardiovascular Prosthetic Devices

§ 870.3250 Vascular clip.

(a) *Identification.* A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.

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

§ 870.3260 Vena cava clip.

(a) *Identification.* A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

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

§ 870.3300 Vascular embolization device.

(a) *Identification.* A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see § 882.5950 of this chapter.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.'' For availability of this guidance document, see § 870.1(e).

[69 FR 77899, Dec. 29, 2004]

§ 870.3375 Cardiovascular intravascular filter.

(a) *Identification.* A cardiovascular intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.

(b) *Classification.* Class II. The special controls for this device are:

(1) ''Use of International Standards Organization's ISO 10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,' '' and

(2) FDA's:

(i) ''510(k) Sterility Review Guidance and Revision of 2/12/90 (K90–1)'' and

(ii) ''Guidance for Cardiovascular Intravascular Filter 510(k) Submissions.''

[45 FR 7907, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.3450 Vascular graft prosthesis.

(a) *Identification.* A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Guidance Document for Vascular Prostheses 510(k) Submissions.''

[66 FR 18542, Apr. 10, 2001]

§ 870.3460 Endovascular Suturing System.

(a) *Identification.* An endovascular suturing system is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery. The system is comprised of the implant device and an endovascular delivery device used to implant the endovascular suture.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device should be demonstrated to be biocompatible;

(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]