

§ 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 Arterial embolization device.

(a) *Identification.* An arterial embolization device is an intravascular implanted device used to control internal hemorrhage or to halt blood flow in arteries supplying blood to certain types of abdominal tumors (e.g., nephroma, hepatoma) and arteriovenous malformations. This device is not used in intracranial arteries.

(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]

§ 870.3375 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 7907-7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 870.3450 Vascular graft prosthesis of less than 6 millimeters diameter.

(a) *Identification.* A vascular graft prosthesis of less than 6 millimeters (mm) diameter is a device used to replace sections of small arteries. This prosthesis is commonly constructed of woven or knitted materials such as polyethylene terephthalate and polytetrafluoroethylene and is not made of materials of animal origin, including human umbilical cords.

(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]

§ 870.3460 Vascular graft prosthesis of 6 millimeters and greater diameter.

(a) *Identification.* A vascular graft prosthesis of 6 millimeters (mm) and greater diameter is a device used to replace sections of arteries. This prosthesis is commonly constructed of woven or knitted materials such as polyethylene terephthalate and polytetrafluoroethylene and is not made of materials of animal origin, including human umbilical cords.

(b) *Classification.* Class II. The stainless steel vascular tunneler of single unit construction to be used to place tunnels for vascular grafts, included as an accessory to the device described in paragraph (a) of this section, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9. All other devices classified in this section are subject to the premarket notification procedures.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 65 FR 11467, Mar. 3, 2000]

§ 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