§ 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 (performance standards).

§ 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 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.”

§ 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 controls for this device are:

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