Food and Drug Administration, HHS

§ 870.3925 Replacement heart valve.

(a) **Identification.** A replacement heart valve is a device intended to perform the function of any of the heart’s natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) **Classification.** Class III (premarket approval).

(c) **Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 870.3850 Carotid sinus nerve stimulator.

(a) **Identification.** A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering’s nerve at the carotid sinus.

(b) **Classification.** Class III (premarket approval).

(c) **Date PMA or notice of completion of a PDP is required.** A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 870.3800 Annuloplasty ring.

(a) **Identification.** An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) **Classification.** Class III (premarket approval). The special control for this device is the FDA guidance document entitled “Guidance for Annuloplasty Rings 510(k) Submissions.”