December 26, 1996 been found to be substantially equivalent to a catheter balloon repair kit that was in commercial distribution before May 28, 1976. Any other catheter balloon repair kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 870.1360 Trace microsphere.

(a) Identification. A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

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

(c) Date PMA or notice of completion of a 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 December 26, 1996 for any trace microsphere 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 trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


§ 870.1370 Catheter tip occluder.

(a) Identification. A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

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

§ 870.1380 Catheter stylet.

(a) Identification. A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

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