Food and Drug Administration, HHS

§ 870.1230 Fiberoptic oximeter catheter.

(a) Identification. A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

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

§ 870.1240 Flow-directed catheter.

(a) Identification. A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.

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

§ 870.1250 Percutaneous catheter.

(a) Identification. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

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

§ 870.1270 Intracavitary phonocatheter system.

(a) Identification. An intracavitary phonocatheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.

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

§ 870.1280 Steerable catheter.

(a) Identification. A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

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

§ 870.1290 Steerable catheter control system.

(a) Identification. A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

(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 catheter balloon repair kit that was in commercial distribution before May 28, 1976, or that has, on or before...