Food and Drug Administration, HHS

§ 870.1310 Vessel dilator for percutaneous catheterization.
(a) Identification. A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.

§ 870.1320 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 II (performance standards).

§ 870.1330 Catheter cannula.
(a) Identification. A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.
(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 bio-acoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.
(b) Classification. Class II (performance standards).

§ 870.1220 Electrode recording catheter or electrode recording probe.
(a) Identification. An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.
(b) Classification. Class II (performance standards).

§ 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).

§ 870.1210 Continuous flush catheter.
(a) Identification. A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.
(b) Classification. Class II (performance standards).

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