record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others. (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).

§ 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).

§ 870.1250 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 II (performance standards).

§ 870.1300 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).

§ 870.1310 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.