§ 870.1130 Noninvasive blood pressure measurement system.

(a) Identification. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body.

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

§ 870.1140 Venous blood pressure manometer.

(a) Identification. A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

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

§ 870.1200 Diagnostic intravascular catheter.

(a) Identification. An intravascular diagnostic catheter is a device used to 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 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 biologic and acoustic 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)