§ 870.1110 Blood pressure computer.
(a) Identification. A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.
(b) Classification. Class II (performance standards).

§ 870.1112 Blood pressure cuff.
(a) Identification. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject’s blood pressure.
(b) Classification. Class II (performance standards).

§ 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.

§ 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.
§ 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).

§ 870.1280 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.
(b) Classification. Class II (performance standards).

§ 870.1320 Catheter guide wire.
(a) Identification. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.
(b) Classification. Class II (performance standards).

§ 870.1340 Catheter introducer.
(a) Identification. A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
(b) Classification. Class II (performance standards).

§ 870.1350 Catheter balloon repair kit.
(a) Identification. A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.
(b) Classification. Class II (performance standards).
(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 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 II (performance standards).
(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.