§ 870.1025 Nucleic acid hybridization technology rather than culture or immunoassay technology; or
(c) The device is an in vitro device that is intended:
(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;
(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;
(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;
(4) For assessing the risk of cardiovascular diseases;
(5) For use in diabetes management;
(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
(8) For noninvasive testing as defined in §812.3(k) of this chapter; and
(9) For near patient testing (point of care).
[68 FR 61344, Oct. 28, 2003]

Subpart B—Cardiovascular Diagnostic Devices

§ 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

(a) Identification. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

(b) Classification. Class II (special controls). The guidance document entitled “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm” will serve as the special control. See §870.1 for the availability of this guidance document.

[68 FR 61344, Oct. 28, 2003]

§ 870.1100 Blood pressure alarm.

(a) Identification. A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.

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

§ 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).

§ 870.1120 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.
(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 electro-cardiogram 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 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
§ 870.1330 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 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 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 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 trace microsphere 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 trace microsphere that was in commercial distribution before May 28, 1976. Any other trace microsphere shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 870.1370 Catheter tip occluder.

(a) Identification. A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

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

§ 870.1380 Catheter stylet.

(a) Identification. A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

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

§ 870.1390 Trocar.

(a) Identification. A trocar is a sharply pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

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

§ 870.1425 Programmable diagnostic computer.

(a) Identification. A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.
§ 870.1435 Single-function, preprogrammed diagnostic computer.

(a) Identification. A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

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

§ 870.1450 Densitometer.

(a) Identification. A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

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

§ 870.1650 Angiographic injector and syringe.

(a) Identification. An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

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

§ 870.1660 Indicator injector.

(a) Identification. An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the bloodstream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

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

§ 870.1670 Syringe actuator for an injector.

(a) Identification. A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

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

§ 870.1750 External programmable pacemaker pulse generator.

(a) Identification. An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

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

§ 870.1800 Withdrawal-infusion pump.

(a) Identification. A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.

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

§ 870.1875 Stethoscope.

(a) Manual stethoscope—(1) Identification. A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

(b) Electronic stethoscope—(1) Identification. An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

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


§ 870.1915 Thermodilution probe.

(a) Identification. A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

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