

**§ 870.1025**

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2314, Jan. 14, 2000]

**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.

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(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 electrocardiogram detection, or may be a

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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.

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

**§ 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