§ 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.

[65 FR 2314, Jan. 14, 2000]

Subpart B—Cardiovascular Diagnostic Devices

§ 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
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§ 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).