§ 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...