§ 870.2750 Impedance phlebograph.

(a) Identification. An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

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

§ 870.2770 Impedance plethysmograph.

(a) Identification. An impedance plethysmograph is a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs.

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

§ 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.

(a) Identification. A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

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

§ 870.2800 Medical magnetic tape recorder.

(a) Identification. A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

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

§ 870.2810 Paper chart recorder.

(a) Identification. A paper chart recorder is a device used to print on paper, and create a permanent record of the signal from, for example, a physiological amplifier, signal conditioner, or computer.

(b) 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.


§ 870.2840 Apex cardiographic transducer.

(a) Identification. An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

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

§ 870.2850 Extravascular blood pressure transducer.

(a) Identification. An extravascular blood pressure transducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to the electrical or mechanical changes produced in the transducer.

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

§ 870.2855 Implantable Intra-aneurysm Pressure Measurement System.

(a) Identification. Implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System.” See §870.1 (e) for the availability of this guidance document.

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§ 870.2860 Heart sound transducer.

(a) Identification. A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

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