

§ 870.2810

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.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 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.

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(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.

[71 FR 7871, Feb. 15, 2006]

§ 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).

§ 870.2870 Catheter tip pressure transducer.

(a) *Identification*. A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

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

§ 870.2880 Ultrasonic transducer.

(a) *Identification*. An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

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

§ 870.2890 Vessel occlusion transducer.

(a) *Identification*. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

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