

§ 870.2320

21 CFR Ch. I (4–1–12 Edition)

§ 870.2320 Ballistocardiograph.

(a) *Identification.* A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.

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

§ 870.2330 Echocardiograph.

(a) *Identification.* An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

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

§ 870.2340 Electrocardiograph.

(a) *Identification.* An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.

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

§ 870.2350 Electrocardiograph lead switching adaptor.

(a) *Identification.* An electrocardiograph lead switching adaptor is a passive switching device to which electrocardiograph limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

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

§ 870.2360 Electrocardiograph electrode.

(a) *Identification.* An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

(b) *Classification.* Class II (special 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. The

special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Electrocardiograph Electrodes.” See § 870.1(e) for availability information of guidance documents.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 76 FR 43585, July 21, 2011]

§ 870.2370 Electrocardiograph surface electrode tester.

(a) *Identification.* An electrocardiograph surface electrode tester is a device used to test the function and application of electrocardiograph electrodes.

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

§ 870.2390 Phonocardiograph.

(a) *Identification.* A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.

(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]

§ 870.2400 Vectorcardiograph.

(a) *Identification.* A vectorcardiograph is a device used to process the electrical signal transmitted through electrocardiograph electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

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

§ 870.2450 Medical cathode-ray tube display.

(a) *Identification.* A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

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