

§ 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).

§ 870.2600 Signal isolation system.

(a) *Identification.* A signal isolation system is a device that electrically isolates the patient from equipment connected to the commercial power supply received from a utility company. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

(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]

§ 870.2620 Line isolation monitor.

(a) *Identification.* A line isolation monitor is a device used to monitor the electrical leakage current from a power supply electrically isolated from the commercial power supply received from a utility company.

(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]

§ 870.2640 Portable leakage current alarm.

(a) *Identification.* A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in