Food and Drug Administration, HHS

§ 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.

§ 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 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).

§ 870.2400 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.

§ 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.

§ 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...