§ 870.2300 Cardiac monitor (including cardiotachometer and rate alarm).

(a) Identification. A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(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 (performance standards).

§ 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.