Food and Drug Administration, HHS

§ 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 subpart E of part 807 of this chapter subject to the limitations in §870.9.

§ 870.2675 Oscillometer.

(a) Identification. An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

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

§ 870.2700 Oximeter.

(a) Identification. An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

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

§ 870.2710 Ear oximeter.

(a) Identification. An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

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

§ 870.2750 Impedance phlebograph.

(a) Identification. An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

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

§ 870.2770 Impedance plethysmograph.

(a) Identification. An impedance plethysmograph is a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs.

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

§ 870.2780 Hydraulic, pneumatic, or photoelectric plethysmographs.

(a) Identification. A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

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

§ 870.2800 Medical magnetic tape recorder.

(a) Identification. A medical magnetic tape recorder is a device used to record 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.

§ 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