Food and Drug Administration, HHS

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

§ 870.1800 Withdrawal-infusion pump.

(a) Identification. A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.

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

§ 870.1875 Stethoscope.

(a) Manual stethoscope—(1) Identification. A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) 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.

(b) Electronic stethoscope—(1) Identification. An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

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


§ 870.1915 Thermodilution probe.

(a) Identification. A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

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

Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) Identification. A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

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

§ 870.2310 Apex cardiograph (vibrocardiograph).

(a) Identification. An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

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