Food and Drug Administration, HHS

§ 870.1660 Indicator injector.

(a) Identification. An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the bloodstream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

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

§ 870.1670 Syringe actuator for an injector.

(a) Identification. A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

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

§ 870.1750 External programmable pacemaker pulse generator.

(a) Identification. An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

(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 II (performance standards).

(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.

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).

§ 870.2060 Transducer signal amplifier and conditioner.

(a) Identification. A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

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

§ 870.2100 Cardiovascular blood flowmeter.

(a) Identification. A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

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

§ 870.2120 Extravascular blood flow probe.

(a) Identification. An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter.