(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 (special controls). The device, when it is a lung sound monitor, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38796, July 25, 2001; 84 FR 71811, Dec. 30, 2019]

§ 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).

§ 870.2060 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 to measure blood flow in a chamber or vessel.

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

§ 870.2200 Adjunctive cardiovascular status indicator.

(a) *Identification.* The adjunctive cardiovascular status indicator is a prescription device based on sensor technology for the measurement of a physical parameter(s). This device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Software description, verification, and validation based on comprehensive hazard analysis must be provided, including:

(i) Full characterization of technical parameters of the software, including any proprietary algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures; and

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on accuracy of patient reports.

(2) Scientific justification for the validity of the status indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm using a data set separate from the training data must demonstrate the validity of modeling.