Food and Drug Administration, HHS

§ 868.1975 Water vapor analyzer.

(a) Identification. A water vapor analyzer is a device intended to measure

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) Identification. An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to a patient’s heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

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

§ 868.1930 Stethoscope head.

(a) Identification. A stethoscope head is a weighted chest piece used during anesthesia to listen to a patient’s heart, breath, and other physiological 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 §868.9.

§ 868.1965 Switching valve (ploss).

(a) Identification. A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen only to a patient’s heart or Korotkoff (blood pressure) sounds through the other channel.

(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 §868.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 868.1910 Esophageal stethoscope.

(a) Identification. An esophageal stethoscope is a nonpowered device that is inserted into a patient’s esophagus to enable the user to listen to heart and breath 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 §868.9.

§ 868.1890 Predictive pulmonary-function value calculator.

(a) Identification. A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

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

§ 868.1880 Pulmonary-function data calculator.

(a) Identification. A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

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

§ 868.1850 Diagnostic pulmonary-function interpretation calculator.

(a) Identification. A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

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

§ 868.1975 Water vapor analyzer.

(a) Identification. A water vapor analyzer is a device intended to measure

the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry.

(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 § 868.9.


**Subpart C—Monitoring Devices**

§ 868.2025 *Ultrasonic air embolism monitor.*

(a) **Identification.** An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's bloodstream. It may use Doppler or other ultrasonic principles.

(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 § 868.9.


§ 868.2300 *Bourdon gauge flowmeter.*

(a) **Identification.** A bourdon gauge flowmeter is a device intended for medical purposes that is used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate when the outflow is open to the atmosphere.

(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 § 868.9.


§ 868.2320 *Uncompensated thorpe tube flowmeter.*

(a) **Identification.** An uncompensated thorpe tube flowmeter is a device intended for medical purposes that is used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(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 § 868.9.


§ 868.2340 *Compensated thorpe tube flowmeter.*

(a) **Identification.** A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(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 § 868.9.


§ 868.2350 *Gas calibration flowmeter.*

(a) **Identification.** A gas calibration flowmeter is a device intended for medical purposes that is used to calibrate flowmeters and accurately measure gas flow.

(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 § 868.9.


§ 868.2375 *Breathing frequency monitor.*

(a) **Identification.** A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits. This device does not include the apnea monitor classified in § 868.2377.

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

[47 FR 31142, July 16, 1982, as amended at 67 FR 46852, July 17, 2002]