§ 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.


§ 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 blood stream. It may use Doppler or other ultrasonic principles.

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

§ 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 control and measure gas flow rate accurately. The device includes an uncompensated 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.