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 indicate and control 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.


§868.2340 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).

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