§ 868.1780 Inspiratory airway pressure meter.

(a) Identification. An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient’s airway during maximal inspiration.

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

§ 868.1800 Rhinoanemometer.

(a) Identification. A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient’s nasal passages.

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

§ 868.1840 Diagnostic spirometer.

(a) Identification. A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient’s lungs.

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

§ 868.1850 Monitoring spirometer.

(a) Identification. A monitoring spirometer is a device used to measure continuously a patient’s tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient’s ventilatory status.

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

§ 868.1860 Peak-flow meter for spirometry.

(a) Identification. A peak-flow meter for spirometry is a device used to measure a patient’s maximum ventilatory flow rate.

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

§ 868.1870 Gas volume calibrator.

(a) Identification. A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(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.


§ 868.1880 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).

§ 868.1890 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).

§ 868.1900 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).

§ 868.1910 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.


§ 868.1920 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 ear-piece. 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.


§ 868.1975 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.