§ 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 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.

§ 868.1975 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.