§ 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 §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