 device is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO₂) and Oxygen (PcO₂) Monitors; Guidance for Industry and FDA.” See §868.1(e) for the availability of this guidance document.

[67 FR 76681, Dec. 13, 2002]

§ 868.2550 Pneumotachometer.
(a) Identification. A pneumotachometer is a device intended for medical purposes that is used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.
(b) Classification. Class II (performance standards).

§ 868.2600 Airway pressure monitor.
(a) Identification. An airway pressure monitor is a device used to measure the pressure in a patient’s upper airway. The device may include a pressure gauge and an alarm.
(b) Classification. Class II (performance standards).

§ 868.2610 Gas pressure gauge.
(a) Identification. A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device intended for medical purposes that is used to measure gas pressure in a medical gas delivery system.
(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.


§ 868.2615 Differential pressure transducer.
(a) Identification. A differential pressure transducer is a two-chambered device intended for medical purposes that is often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.
(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.