to monitor nitrogen dioxide levels during inhaled nitric oxide therapy, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The special control is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.'' See § 868.1(e) for the availability of this guidance document.

[65 FR 11465, Mar. 3, 2000, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any lung water monitor that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a lung water monitor that was in commercial distribution before May 28, 1976. Any other lung water monitor device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 65 FR 19834, Apr. 13, 2000]

§ 868.2480 Cutaneous carbon dioxide (PcCO2) monitor.

(a) *Identification.* A cutaneous carbon dioxide (PcCO2) monitor is a noninvasive heated sensor and a pH-sensitive glass electrode placed on a patient's skin, which is intended to monitor relative changes in a hemodynamically stable patient's cutaneous carbon dioxide tension as an adjunct to arterial carbon dioxide tension measurement.

(b) *Classification.* Class II (special controls). The special control for this 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.

[54 FR 27160, June 28, 1989, as amended at 67 FR 76681, Dec. 13, 2002]

§ 868.2500 Cutaneous oxygen (PcO2) monitor.

(a) *Identification.* A cutaneous oxygen (PcO2) monitor is a noninvasive, heated sensor (e.g., a Clark-type polargraphic electrode) placed on the patient's skin that is intended to monitor relative changes in the cutaneous oxygen tension.

(b) *Classification.* Class II (special 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 special control 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, as amended at 84 FR 71811, Dec. 30, 2019]

§ 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 (special 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.

[47 FR 31142, July 16, 1982, as amended at 84 FR 71811, Dec. 30, 2019]

§ 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.