§ 868.2385 Nitrogen dioxide analyzer.

(a) Identification. The nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

(b) Classification. Class II. The special control for this device is FDA’s “Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.”

[65 FR 14465, Mar. 3, 2000]

§ 868.2385 Cutaneous carbon dioxide \((\text{PcCO}_2)\) monitor.

(a) Identification. A cutaneous carbon dioxide \((\text{PcCO}_2)\) 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 (\text{PcCO}_2) and Oxygen (\text{PcO}_2) Monitors; Guidance for Industry and FDA.” See §868.1(e) for the availability of this guidance document.


§ 868.2500 Cutaneous oxygen \((\text{PcO}_2)\) monitor.

(a) Identification. A cutaneous oxygen \((\text{PcO}_2)\) monitor is a noninvasive, heated sensor (e.g., a Clark-type polarographic 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 special control for this device is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (\text{PcCO}_2) and Oxygen (\text{PcO}_2) 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