

**§ 868.1100**

(b) *Classification.* Class II (performance standards).

**§ 868.1100 Arterial blood sampling kit.**

(a) *Identification.* An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

**§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.**

(a) *Identification.* An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

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

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to an indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976. Any other indwelling blood oxyhemoglobin concentration analyzer 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; 52 FR 22577, June 12, 1987; 69 FR 34920, June 23, 2004]

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**§ 868.1150 Indwelling blood carbon dioxide partial pressure (P<sub>CO2</sub>) analyzer.**

(a) *Identification.* An indwelling blood carbon dioxide partial pressure P<sub>CO2</sub> analyzer is a device that consists of a catheter-tip P<sub>CO2</sub> transducer (e.g., P<sub>CO2</sub> electrode) and that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA."

[47 FR 31142, July 16, 1982; 47 FR 40410, Sept. 14, 1982, as amended at 52 FR 17735, May 11, 1987; 66 FR 57368, Nov. 15, 2001]

**§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.**

(a) *Identification.* An indwelling blood hydrogen ion concentration (pH) analyzer is a device that consists of a catheter-tip pH electrode and that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA."

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 66 FR 57368, Nov. 15, 2001]

**§ 868.1200 Indwelling blood oxygen partial pressure (P<sub>O2</sub>) analyzer.**

(a) *Identification.* An indwelling blood oxygen partial pressure (P<sub>O2</sub>) analyzer is a device that consists of a catheter-tip P<sub>O2</sub> transducer (e.g., P<sub>O2</sub> electrode) and that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Indwelling