§ 868.1040 Powered algesimeter.

(a) Identification. A powered algesimeter is a device using electrical stimulation intended to determine a patient’s sensitivity to pain after administration of an anesthetic agent.

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

§ 868.1075 Argon gas analyzer.

(a) Identification. An argon gas analyzer is a device intended to measure the concentration of argon in a gas mixture to aid in determining the patient’s ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

(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).

§ 868.1120 Indwelling blood oxygen hemoglobin concentration analyzer.

(a) Identification. An indwelling blood oxygen hemoglobin 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 oxygen hemoglobin 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 oxygen hemoglobin concentration analyzer that was in commercial distribution before May 28, 1976. Any other indwelling blood oxygen hemoglobin concentration analyzer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P_CO2) analyzer.

(a) Identification. An indwelling blood carbon dioxide partial pressure P_CO2 analyzer is a device that consists of a catheter-tip P_CO2 transducer (e.g., P_CO2 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.”

§ 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