§ 868.1030 Manual algesimeter.

(a) Identification. A manual algesimeter is a mechanical device intended to determine a patient’s sensitivity to pain after administration of an anesthetic agent, e.g., by pricking with a sharp point.

(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. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 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). 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.

§ 868.1120 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