§ 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.

[65 FR 2313, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 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...
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§ 868.1430 Carbon monoxide gas analyzer.

(a) Identification. A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient’s ventilatory status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

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

§ 868.1430 Carbon monoxide gas analyzer.

(a) Identification. A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient’s ventilatory status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

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