

from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976, e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[54 FR 25047, June 12, 1989]

Subpart B—Diagnostic Devices

§ 868.1030 Manual algometer.

(a) *Identification.* A manual algometer 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations 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.

[54 FR 25048, June 12, 1989]

§ 868.1040 Powered algometer.

(a) *Identification.* A powered algometer is a device using electrical stimu-

lation 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. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996]

§ 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 a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 868.3.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 52 FR 22577, June 12, 1987]

§ 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,