nucleic acid hybridization technology rather than culture or immunoassay technology; or

c The device is an in vitro device that is intended:

1. For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;
2. For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;
3. For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;
4. For assessing the risk of cardiovascular diseases;
5. For use in diabetes management;
6. For identifying or inferring the identity of a microorganism directly from clinical material;
7. For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
8. For noninvasive testing as defined in §812.3(k) of this chapter; and
9. For near patient testing (point of care).

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§ 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.

[54 FR 25048, June 12, 1989, as amended at 66 FR 38793, July 25, 2001]

§ 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 being placed in commercial distribution.

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P\(_{\text{CO}_2}\)) analyzer.

(a) Identification. An indwelling blood carbon dioxide partial pressure P\(_{\text{CO}_2}\) analyzer is a device that consists of a catheter-tip P\(_{\text{CO}_2}\) transducer (e.g., P\(_{\text{CO}_2}\) 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 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.”

§ 868.1200 Indwelling blood oxygen partial pressure (P\(_{\text{O}_2}\)) analyzer.

(a) Identification. An indwelling blood oxygen partial pressure (P\(_{\text{O}_2}\)) analyzer is a device that consists of a catheter-tip P\(_{\text{O}_2}\) transducer (e.g., P\(_{\text{O}_2}\) 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 Blood Gas Analyzers; Final Guidance for Industry and FDA.”

§ 868.1400 Carbon dioxide gas analyzer.

(a) Identification. A carbon dioxide gas analyzer is a device intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient’s ventilatory, circulatory, and metabolic 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 infrared absorption or gas chromatography.

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