(B) For representative mutations of those designated as cancer mutations with evidence of clinical significance, a description of the clinical evidence associated with such mutations, such as clinical evidence presented in professional guidelines, as appropriate, with method comparison performance data as described in paragraph (b)(1)(iv)(G) of this section.

(C) For all other mutations designated as cancer mutations with potential clinical significance, a description of the rationale for reporting.

(2) The 21 CFR 809.10 compliant labeling and any product information and test report generated, must include the following, as applicable:

(i) The intended use statement must specify the following:

(A) The test is indicated for previously diagnosed cancer patients.

(B) The intended specimen type(s) and matrix (*e.g.*, formalin-fixed, paraffin-embedded tumor tissue).

(C) The mutation types (*e.g.*, single nucleotide variant, insertion, deletion, copy number variation or gene rearrangement) for which validation data has been provided.

(D) The name of the testing facility or facilities, as applicable.

(ii) A description of the device and summary of the results of the performance studies performed in accordance with paragraphs (b)(1)(iii), (b)(1)(iv), and (b)(1)(v) of this section.

(iii) A description of applicable test limitations, including, for device specific mutations validated with method comparison data to a medically established test in the same intended specimen type, appropriate description of the level of evidence and/or the differences between next generation sequencing results and results from the medically established test (*e.g.*, as described in professional guidelines).

(iv) A listing of all somatic mutations that are intended to be detected by the device and that are reported in the test results under the following two categories or equivalent designations, as appropriate: ''cancer mutations panel with evidence of clinical significance'' or ''cancer mutations panel with potential clinical significance.''

(v) For mutations reported under the category of ''cancer mutations panel with potential clinical significance,'' a limiting statement that states ''For the mutations listed in [cancer mutations panel with potential clinical significance or equivalent designation], the clinical significance has not been demonstrated [with adequate clinical evidence (*e.g.*, by professional guidelines) in accordance with paragraph (b)(1)(v) of this section] or with this test.''

(vi) For mutations under the category of ''cancer mutations panel with evidence of clinical significance,'' or equivalent designation, link(s) for physicians to access internal or external information concerning decision rules or conclusions about the level of evidence for clinical significance that is associated with the marker in accordance with paragraph (b)(1)(v) of this section.

[83 FR 28995, June 22, 2018]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Subpart C—Monitoring Devices

Subparts D–E [Reserved]

Subpart F—Therapeutic Devices

Subpart G—Miscellaneous

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

SOURCE: 47 FR 31142, July 16, 1982, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 868 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by §807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

[52 FR 17734, May 11, 1987, as amended at 67 FR 76681, Dec. 13, 2002; 78 FR 18233, Mar. 26, 2013]

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the

device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17734, May 11, 1987]

§ 868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption 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 the intended use of a legally marketed device in that generic type of device; 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;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; 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 deoxyribonucleic acid (DNA) probe or 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).

[65 FR 2313, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 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 (special 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.

[47 FR 31142, July 16, 1982, as amended at 84 FR 71811, Dec. 30, 2019]

§ 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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 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.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 52 FR 22577, June 12, 1987; 69 FR 34920, June 23, 2004]

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P_{2CO2}) 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.''

[47 FR 31142, July 16, 1982; 47 FR 40410, Sept. 14, 1982, as amended at 52 FR 17735, May 11, 1987; 66 FR 57368, Nov. 15, 2001]

§ 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.''

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 66 FR 57368, Nov. 15, 2001]

§ 868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.

(a) *Identification.* An indwelling blood oxygen partial pressure (P_{O2}) analyzer is a device that consists of a catheter-tip P_{O2} transducer (e.g., P_{O2} 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.''

[47 FR 31142, July 16, 1982; 47 FR 40410, Sept. 14, 1982, as amended at 52 FR 17735, May 11, 1987; 66 FR 57368, Nov. 15, 2001]

§ 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).

§ 868.1500 Enflurane gas analyzer.

(a) *Identification.* An enflurane gas analyzer is a device intended to measure the concentration of enflurane anesthetic in a gas mixture.

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

§ 868.1505 Ventilatory electrical impedance tomograph.

(a) *Identification.* A ventilatory electrical impedance tomograph is a prescription non-invasive, non-radiological ventilatory device that provides an assessment of local impedance variation within a cross-section of a patient's thorax.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Characterization of device parameters, including signal-to-noise ratio, voltage accuracy, drift, reciprocity accuracy, amplitude response, position error, and ringing;

(ii) Real time evaluation of local impedance variation;

(iii) Plethysmogram accuracy testing; and

(iv) Use life testing of reusable components.

(3) Performance data must validate reprocessing instructions for any reusable components of the device.

(4) Performance data must demonstrate the electrical, thermal, and mechanical safety and the electromagnetic compatibility of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include the following:

(i) Guidance for interpretation of the images generated;

(ii) A warning that the device should be removed before use of a defibrillator, or defibrillator interaction information based on defibrillator performance testing with the device;

(iii) A use life for any reusable components; and

(iv) Instructions for reprocessing any reusable components.

[84 FR 15098, Apr. 15, 2019]

§ 868.1575 Gas collection vessel.

(a) *Identification.* A gas collection vessel is a container-like device intended to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 868.1620 Halothane gas analyzer.

(a) *Identification.* A halothane gas analyzer is a device intended to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared or ultraviolet radiation.

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

§ 868.1640 Helium gas analyzer.

(a) *Identification.* A helium gas analyzer is a device intended to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

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

§ 868.1670 Neon gas analyzer.

(a) *Identification.* A neon gas analyzer is a device intended to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

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

§ 868.1690 Nitrogen gas analyzer.

(a) *Identification.* A nitrogen gas analyzer is a device intended to measure the concentration of nitrogen in respiratory gases to aid in determining a patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

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

§ 868.1700 Nitrous oxide gas analyzer.

(a) *Identification.* A nitrous oxide gas analyzer is a device intended to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

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

§ 868.1720 Oxygen gas analyzer.

(a) *Identification.* An oxygen gas analyzer is a device intended to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polarography, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

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

§ 868.1730 Oxygen uptake computer.

(a) *Identification.* An oxygen uptake computer is a device intended to compute the amount of oxygen consumed by a patient and may include components for determining expired gas volume and composition.

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

§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

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

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which a patient sits, that is used to determine the patient's lung volume changes.

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

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

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

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

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

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

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

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

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

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

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

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

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

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

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

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

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

§ 868.1910 Esophageal stethoscope.

(a) *Identification.* An esophageal stethoscope is a nonpowered device that is inserted into a patient's esophagus to enable the user to listen to heart and breath sounds.

(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 § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) *Identification.* An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to a patient's heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

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

§ 868.1930 Stethoscope head.

(a) *Identification.* A stethoscope head is a weighted chest piece used during anesthesia to listen to a patient's heart, breath, and other physiological sounds.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38793, July 25, 2001]

§ 868.1965 Switching valve (ploss).

(a) *Identification.* A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen only to a patient's heart or korotkoff (blood pressure) sounds through the other channel.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38793, July 25, 2001]

§ 868.1975 Water vapor analyzer.

(a) *Identification.* A water vapor analyzer is a device intended to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

Subpart C—Monitoring Devices

§ 868.2025 Ultrasonic air embolism monitor.

(a) *Identification.* An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

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

§ 868.2300 Bourdon gauge flowmeter.

(a) *Identification.* A bourdon gauge flowmeter is a device intended for medical purposes that is used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate when the outflow is open to the atmosphere.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2320 Uncompensated thorpe tube flowmeter.

(a) *Identification.* An uncompensated thorpe tube flowmeter is a device intended for medical purposes that is used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device intended for medical purposes that is used to calibrate flowmeters and accurately measure gas flow.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits. This device does not include the apnea monitor classified in § 868.2377.

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

[47 FR 31142, July 16, 1982, as amended at 67 FR 46852, July 17, 2002]

§ 868.2377 Apnea monitor.

(a) *Identification.* An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA.''

[67 FR 46852, July 17, 2002]

§ 868.2380 Nitric oxide analyzer.

(a) *Identification.* The nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.''

[65 FR 14465, Mar. 3, 2000]

§ 868.2385 Nitrogen dioxide analyzer.

(a) *Identification.* The nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

(b) *Classification.* Class II (special controls). The device, when it is a standalone nitrogen dioxide analyzer and not those that are components of nitric oxide delivery systems intended

to monitor nitrogen dioxide levels during inhaled nitric oxide therapy, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9. The special control is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.'' See §868.1(e) for the availability of this guidance document.

[65 FR 11465, Mar. 3, 2000, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 12, 2000, for any lung water monitor that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a lung water monitor that was in commercial distribution before May 28, 1976. Any other lung water monitor device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 65 FR 19834, Apr. 13, 2000]

§ 868.2480 Cutaneous carbon dioxide (PcCO2) monitor.

(a) *Identification.* A cutaneous carbon dioxide (PcCO2) monitor is a noninvasive heated sensor and a pH-sensitive glass electrode placed on a patient's skin, which is intended to monitor relative changes in a hemodynamically stable patient's cutaneous carbon dioxide tension as an adjunct to arterial carbon dioxide tension measurement.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA.'' See §868.1(e) for the availability of this guidance document.

[54 FR 27160, June 28, 1989, as amended at 67 FR 76681, Dec. 13, 2002]

§ 868.2500 Cutaneous oxygen (PcO2) monitor.

(a) *Identification.* A cutaneous oxygen (PcO2) monitor is a noninvasive, heated sensor (e.g., a Clark-type polargraphic electrode) placed on the patient's skin that is intended to monitor relative changes in the cutaneous oxygen tension.

(b) *Classification.* Class II (special 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 special control is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA.'' See §868.1(e) for the availability of this guidance document.

[67 FR 76681, Dec. 13, 2002, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.2550 Pneumotachometer.

(a) *Identification.* A pneumotachometer is a device intended for medical purposes that is used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

(b) *Classification.* Class II (special 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.

[47 FR 31142, July 16, 1982, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.2600 Airway pressure monitor.

(a) *Identification.* An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

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

§ 868.2610 Gas pressure gauge.

(a) *Identification.* A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device intended for medical purposes that is used to measure gas pressure in a medical gas delivery system.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2620 Gas pressure calibrator.

(a) *Identification.* A gas pressure calibrator is a device intended for medical purposes that is used to calibrate pressure-measuring instruments by generating a known gas pressure.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2700 Pressure regulator.

(a) *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2775 Electrical peripheral nerve stimulator.

(a) *Identification.* An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

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

§ 868.2875 Differential pressure transducer.

(a) *Identification.* A differential pressure transducer is a two-chambered device intended for medical purposes that is often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2885 Gas flow transducer.

(a) *Identification.* A gas flow transducer is a device intended for medical purposes that is used to convert gas flow rate into an electrical signal for subsequent display or processing.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2900 Gas pressure transducer.

(a) *Identification.* A gas pressure transducer is a device intended for medical purposes that is used to convert gas pressure into an electrical signal for subsequent display or processing.

(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 1120, Jan. 16, 1996]

Subparts D–E [Reserved]

Subpart F—Therapeutic Devices

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device intended to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.

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

§ 868.5095 Retrograde intubation device.

(a) *Identification.* A retrograde intubation device is a prescription device used to perform retrograde intubation via the cricothyroid membrane. The device may contain or be labeled for use with guidewires and intubating catheters, in addition to needles (§ 868.5090), syringe (§ 880.5860 of this chapter), and hemostats (§ 878.4800 of this chapter).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Wire guide tensile, flex, fracture, and corrosion testing;

(ii) Catheter tensile strength testing at likely points of failure;

(iii) Catheter kink radius testing;

(iv) Compatibility of device components that interact, including compatibility in connection, disconnection, and ability to transfer fluids;

(v) Dimensional validation;

(vi) Accuracy testing of markings; and

(vii) Validation of the maximum airway pressure.

(2) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(3) The device must be demonstrated to be biocompatible.

(4) Labeling must include:

(i) Instructions for use; and

(ii) Package labels that clearly identify the minimum compatible size of endotracheal tube.

[86 FR 73678, Dec. 28, 2021]

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5105 External negative pressure airway aid.

(a) *Identification.* An external negative pressure airway aid is a prescription device that applies negative pressure to a patient's neck to aid in providing a patent airway during procedures requiring anesthesia.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must document any adverse events observed during clinical use, including impaired blood flow, and demonstrate that the device performs as intended under anticipated conditions.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated patient positions, does not fail during use, and does not lose negative pressure capability. The following testing should be performed:

(i) Ability of the device to maintain a seal during various patient positions;

(ii) Device leakage testing to demonstrate the device maintains vacuum;

(iii) Drop testing to ensure the device does not incur functional damage after dropping the device; and

(iv) Functional testing after high and low storage temperature.

(3) All patient contacting components must be demonstrated to be biocompatible.

(4) Labeling must include:

(i) A summary of clinical testing results, including any adverse events and evidence that effectiveness has been achieved.

(ii) Technical specifications of the device, including collar sizes, maximum duration of use, operating temperature, and storage temperature range.

(iii) Technical specifications of the vacuum source, including maximum vacuum level and operational vacuum level.

(iv) Instructions for use that includes how to place the device, determination of size, verification of suction, reference to training materials, and information on troubleshooting the device if it does not attach properly.

(v) A warning to screen patients for carotid artery disease due to the probable risk of the device to dislodge arterial plaques in the carotid artery.

(vi) A warning to exclude patients with anatomical abnormalities.

(vii) A warning not to use the device during medical procedures involving medications that contain propofol.

[82 FR 60867, Dec. 26, 2017]

§ 868.5110 Oropharyngeal airway.

(a) *Identification.* An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5115 Device to relieve acute upper airway obstruction.

(a) *Identification.* The device is a raised, rounded pad that, in the event of choking on a foreign body, can be applied to the abdomen and pushed upward to generate expulsion pressure to remove the obstruction to relieve acute upper airway obstruction.

(b) *Classification.* Class II (special controls) (''Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices''). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to § 868.9.

[65 FR 39099, June 23, 2000; 65 FR 47669, Aug. 3, 2000]

§ 868.5120 Anesthesia conduction catheter.

(a) *Identification.* An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.

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

§ 868.5130 Anesthesia conduction filter.

(a) *Identification.* An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

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

§ 868.5140 Anesthesia conduction kit.

(a) *Identification.* An anesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anesthesia. The device may contain syringes, needles, and drugs.

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

§ 868.5150 Anesthesia conduction needle.

(a) *Identification.* An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

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

§ 868.5160 Gas machine for anesthesia or analgesia.

(a) *Gas machine for anesthesia*—(1) *Identification.* A gas machine for anesthesia is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.

(2) *Classification.* Class II (performance standards).

(b) *Gas machine for analgesia*—(1) *Identification.* A gas machine for analgesia is a device used to administer to a patient an analgesic agent, such as a nitrous oxide-oxygen mixture (maximum concentration of 70 percent nitrous oxide).

(2) *Classification.* Class II (performance standards).

§ 868.5165 Nitric oxide administration apparatus.

(a) *Identification.* The nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.''

[65 FR 11465, Mar. 3, 2000]

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) *Identification.* A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

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

§ 868.5180 Rocking bed.

(a) *Identification.* A rocking bed is a device intended for temporary use to help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

(b) *Classification.* Class II (special 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.

[47 FR 31142, July 16, 1982, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.5220 Blow bottle.

(a) *Identification.* A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(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. If the device is not labeled or otherwise represented as sterile, it is 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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38794, July 25, 2001]

§ 868.5240 Anesthesia breathing circuit.

(a) *Identification.* An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5250 Breathing circuit circulator.

(a) *Identification.* A breathing circuit circulator is a turbine device that is attached to a closed breathing circuit and that is intended to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.

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

§ 868.5260 Breathing circuit bacterial filter.

(a) *Identification.* A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit.

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

§ 868.5270 Breathing system heater.

(a) *Identification.* A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.

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

§ 868.5273 Positive airway pressure delivery system.

(a) *Identification.* A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Waveform testing must simulate breathing conditions and evaluate pressure and airflow response over a range and combination of high and low breath rates and tidal volumes.

(ii) Use life testing must demonstrate adequate device performance over the labeled use life of the device.

(iii) Device integrity testing must demonstrate that the device can withstand typical forces expected during use.

(iv) Carbon dioxide rebreathing testing must be performed.

(v) System flow rate, maximum expiratory pressure, inhalation pressure, and intra-mask static pressure testing must be performed.

(vi) Air bolus testing must demonstrate that the device can withstand worst-case scenario air pressures.

(vii) Maximum limited pressure testing of the flow generator in single fault condition must be performed.

(viii) Maximum output temperature testing of delivered gas, if humidified, must be performed.

(3) Performance data must validate reprocessing instructions for any reusable components of the device.

(4) Performance data must demonstrate the electrical, thermal, and mechanical safety and the electromagnetic compatibility of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include the following:

(i) Therapy pressure range;

(ii) Use life and replacement schedule for all components;

(iii) Cleaning instructions; and

(iv) Instructions for assembly and connection of device components.

[83 FR 52966, Oct. 19, 2018]

§ 868.5280 Breathing tube support.

(a) *Identification.* A breathing tube support is a device that is intended to support and anchor a patient's breathing tube(s).

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38794, July 25, 2001]

§ 868.5300 Carbon dioxide absorbent.

(a) *Identification.* A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5310 Carbon dioxide absorber.

(a) *Identification.* A carbon dioxide absorber is a device that is intended for medical purposes and that is used in a breathing circuit as a container for

carbon dioxide absorbent. It may include a canister and water drain.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5320 Reservoir bag.

(a) *Identification.* A reservoir bag is a device, usually made of conductive rubber, intended for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5330 Breathing gas mixer.

(a) *Identification.* A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.

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

§ 868.5340 Nasal oxygen cannula.

(a) *Identification.* A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils.

(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.

[47 FR 31142, July 16, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38794, July 25, 2001]

§ 868.5350 Nasal oxygen catheter.

(a) *Identification.* A nasal oxygen catheter is a device intended to be inserted through a patient's nostril to administer oxygen.

(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.

[47 FR 31142, July 16, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38794, July 25, 2001]

§ 868.5365 Posture chair for cardiac or pulmonary treatment.

(a) *Identification.* A posture chair for cardiac or pulmonary treatment is a device intended to assist in the rehabilitation and mobilization of patients with chronic heart or lung disease.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38794, July 25, 2001]

§ 868.5375 Heat and moisture condenser (artificial nose).

(a) *Identification.* A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5400 Electroanesthesia apparatus.

(a) *Identification.* An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to a patient's head.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a 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 December 26, 1996

for any electroanesthesia apparatus that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an electroanesthesia apparatus that was in commercial distribution before May 28, 1976. Any other electroanesthesia apparatus shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[47 FR 31142, July 16, 1982, as amended at 52 FR 17735, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 868.5420 Ether hook.

(a) *Identification.* An ether hook is a device that fits inside a patient's mouth and that is intended to deliver vaporized ether.

(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. If the device is not labeled or otherwise represented as sterile, it is 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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38795, July 25, 2001]

§ 868.5430 Gas-scavenging apparatus.

(a) *Identification.* A gas-scavenging apparatus is a device intended to collect excess anesthetic, analgesic, or trace gases or vapors from a patient's breathing system, ventilator, or extracorporeal pump-oxygenator, and to conduct these gases out of the area by means of an exhaust system.

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

§ 868.5440 Portable oxygen generator.

(a) *Identification.* A portable oxygen generator is a device that is intended to release oxygen for respiratory therapy by means of either a chemical reaction or physical means (e.g., a molecular sieve).

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

§ 868.5450 Respiratory gas humidifier.

(a) *Identification.* A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

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

§ 868.5454 High flow humidified oxygen delivery device.

(a) *Identification.* A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:

(i) Alarm testing must be performed;

(ii) Continuous use thermal stability testing must be performed;

(iii) Humidity output testing must be performed; and

(iv) Blender performance testing must evaluate fraction of inspired oxygen (FiO_2) blending accuracy.

(3) Performance data must validate cleaning instructions for any reusable components of the device.

(4) Electrical safety, thermal safety, mechanical safety, electromagnetic compatibility, and radiofrequency identification testing must be performed.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:

(i) A description of available FiO_2 ranges for different flowrates and inlet gas pressures;

(ii) Instructions for applicable flowrates for all intended populations;

(iii) A warning that patients on high flow oxygen are acute and require appropriate monitoring, to include pulse oximetry;

(iv) A warning regarding the risk of condensation at low set temperatures and certain flows; and

(v) A description of all alarms and their functions.

[83 FR 54007, Oct. 26, 2018]

§ 868.5460 Therapeutic humidifier for home use.

(a) *Identification.* A therapeutic humidifier for home use is a device that adds water vapor to breathing gases and that is intended for respiratory therapy or other medical purposes. The vapor produced by the device pervades the area surrounding the patient, who breathes the vapor during normal respiration.

(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.

[47 FR 31142, July 16, 1982; 47 FR 40410, Sept. 14, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. This device does not include topical oxygen chambers for extremities (§ 878.5650).

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

§ 868.5480 Isocapnic ventilation device.

(a) *Identification.* An isocapnic ventilation device is a prescription device used to administer a blend of carbon dioxide and oxygen gases to a patient to induce hyperventilation. This device may be labeled for use with breathing circuits made of reservoir bags (§ 868.5320), oxygen cannulas (§ 868.5340), masks (§ 868.5550), valves (§ 868.5870), resuscitation bags (§ 868.5915), and/or tubing (§ 868.5925).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Nonclinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use, including the following performance characteristics:

(i) Gas concentration accuracy testing for the range of intended concentrations;

(ii) Airway pressure delivery accuracy testing;

(iii) Supplemental O_2 flowrate accuracy testing;

(iv) Alarm testing; and

(v) Use life testing.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Labeling must include the following:

(i) Instructions for use;

(ii) A precaution that monitoring of capnography is necessary during treatment with non-spontaneously breathing patients; and

(iii) Use life specification.

[86 FR 68397, Dec. 2, 2021]

§ 868.5530 Flexible laryngoscope.

(a) *Identification.* A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.

(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.

[47 FR 41107, Sept. 17, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5540 Rigid laryngoscope.

(a) *Identification.* A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.

(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

[47 FR 41107, Sept. 17, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5550 Anesthetic gas mask.

(a) *Identification.* An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.

(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.

[47 FR 41107, Sept. 17, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5560 Gas mask head strap.

(a) *Identification.* A gas mask head strap is a device used to hold an anesthetic gas mask in position on a patient's face.

(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.

[47 FR 41107, Sept. 17, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38795, July 25, 2001]

§ 868.5570 Nonrebreathing mask.

(a) *Identification.* A nonrebreathing mask is a device fitting over a patient's face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5580 Oxygen mask.

(a) *Identification.* An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5590 Scavenging mask.

(a) *Identification.* A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5600 Venturi mask.

(a) *Identification.* A venturi mask is a device containing an air-oxygen mixing mechanism that dilutes 100 percent oxygen to a predetermined concentration and delivers the mixed gases to a patient.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5620 Breathing mouthpiece.

(a) *Identification.* A breathing mouthpiece is a rigid device that is inserted into a patient's mouth and that connects with diagnostic or therapeutic respiratory devices.

(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 § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5630 Nebulizer.

(a) *Identification.* A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

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

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(a) *Identification.* A medicinal nonventilatory nebulizer (atomizer) is a device that is intended to spray liquid medication in aerosol form into the air that a patient will breathe.

(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 § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5650 Esophageal obturator.

(a) *Identification.* An esophageal obturator is a device inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.

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

§ 868.5655 Portable liquid oxygen unit.

(a) *Identification.* A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is intended to supplement gases to be inhaled by a patient, is sometimes accompanied by tubing and an oxygen mask. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

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

§ 868.5665 Powered percussor.

(a) *Identification.* A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.

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

§ 868.5675 Rebreathing device.

(a) *Identification.* A rebreathing device is a device that enables a patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(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 § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5690 Incentive spirometer.

(a) *Identification.* An incentive spirometer is a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation.

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

§ 868.5700 Nonpowered oxygen tent.

(a) *Identification.* A nonpowered oxygen tent is a device that encloses a patient's head and upper body to contain oxygen delivered to the patient for breathing. This generic type of device includes infant oxygen hoods.

(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 § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2313, Jan. 14, 2000]

§ 868.5710 Electrically powered oxygen tent.

(a) *Identification.* An electrically powered oxygen tent is a device that encloses a patient's head and, by means of an electrically powered unit, administers breathing oxygen and controls the temperature and humidity of the breathing gases. This generic type device includes the pediatric aerosol tent.

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

§ 868.5720 Bronchial tube.

(a) *Identification.* A bronchial tube is a device used to differentially intubate a patient's bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

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

§ 868.5730 Tracheal tube.

(a) *Identification.* A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

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

§ 868.5740 Tracheal/bronchial differential ventilation tube.

(a) *Identification.* A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.

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

§ 868.5750 Inflatable tracheal tube cuff.

(a) *Identification.* An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient's trachea.

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

§ 868.5760 Cuff spreader.

(a) *Identification.* A cuff spreader is a device used to install tracheal tube cuffs on tracheal or tracheostomy tubes.

(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. If the device is not labeled or otherwise represented as sterile, it is 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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38795, July 25, 2001]

§ 868.5770 Tracheal tube fixation device.

(a) *Identification.* A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5780 Tube introduction forceps.

(a) *Identification.* Tube introduction forceps (e.g., Magill forceps) are a right-angled device used to grasp a tracheal tube and place it in a patient's trachea.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5790 Tracheal tube stylet.

(a) *Identification.* A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5795 Tracheal tube cleaning brush.

(a) *Identification.* A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.

(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. If the device is not labeled or otherwise represented as sterile, it is 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.

[51 FR 40388, Nov. 6, 1986, as amended at 66 FR 38795, July 25, 2001]

§ 868.5800 Tracheostomy tube and tube cuff.

(a) *Identification.* A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) *Classification.* Class II.

[51 FR 40389, Nov. 6, 1986]

§ 868.5810 Airway connector.

(a) *Identification.* An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5820 Dental protector.

(a) *Identification.* A dental protector is a device intended to protect a patient's teeth during manipulative procedures within a patient's oral cavity.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

§ 868.5830 Autotransfusion apparatus.

(a) *Identification.* An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

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

§ 868.5860 Pressure tubing and accessories.

(a) *Identification.* Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.5870 Nonrebreathing valve.

(a) *Identification.* A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

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

§ 868.5880 Anesthetic vaporizer.

(a) *Identification.* An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

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

§ 868.5895 Continuous ventilator.

(a) *Identification.* A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

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

§ 868.5905 Noncontinuous ventilator (IPPB).

(a) *Identification.* A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.

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

§ 868.5915 Manual emergency ventilator.

(a) *Identification.* A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

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

§ 868.5925 Powered emergency ventilator.

(a) *Identification.* A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

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

§ 868.5935 External negative pressure ventilator.

(a) *Identification.* An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.

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

§ 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification.* An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

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

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification.* A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

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

§ 868.5975 Ventilator tubing.

(a) *Identification.* Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.5995 Tee drain (water trap).

(a) *Identification.* A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

Subpart G—Miscellaneous

§ 868.6100 Anesthetic cabinet, table, or tray.

(a) *Identification.* An anesthetic cabinet, table, or tray is a device intended to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6175 Cardiopulmonary emergency cart.

(a) *Identification.* A cardiopulmonary emergency cart is a device intended to store and transport resuscitation supplies for emergency treatment. The device does not include any equipment used in cardiopulmonary resuscitation.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6225 Nose clip.

(a) *Identification.* A nose clip is a device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6250 Portable air compressor.

(a) *Identification.* A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.

(b) *Classification.* Class II (special 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.

[47 FR 31142, July 16, 1982, as amended at 84 FR 71811, Dec. 30, 2019]

§ 868.6400 Calibration gas.

(a) *Identification.* A calibration gas is a device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6700 Anesthesia stool.

(a) *Identification.* An anesthesia stool is a device intended for use as a stool for the anesthesiologist in the operating room.

(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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25049, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification.* A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification.* Class 1 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 868.9.

[47 FR 31142, July 16, 1982, as amended at 65 FR 2314, Jan. 14, 2000]

§ 868.6820 Patient position support.

(a) *Identification.* A patient position support is a device intended to maintain the position of an anesthetized patient during surgery.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 868.6885 Medical gas yoke assembly.

(a) *Identification.* A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases

for anesthesia or respiratory therapy. The device may include a particulate filter.

(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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Subpart B—Cardiovascular Diagnostic Devices

Subpart C—Cardiovascular Monitoring Devices