(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