(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