(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]