§ 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 II (performance standards).

§ 868.5460 The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

§ 868.5530 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 II (performance standards).

§ 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.

§ 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.

§ 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.

§ 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.