§ 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.

§ 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.

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.

§ 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.
§ 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.


§ 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 (performance standards).

§ 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.


§ 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.


§ 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 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.


§ 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.


§ 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