(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.


§ 868.6225 **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 §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