Food and Drug Administration, HHS

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.
- [47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 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.
- (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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 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 ex-

ception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989; 66 FR 38796, July 25, 2001]

$\S 868.6250$ 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.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§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.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25049, June 12, 1989; 66 FR 38796, July 25, 2001]

§ 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 1 (general controls). The device is exempt from the premarket notification procedures in