§ 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 1 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §868.9.

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§ 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 premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

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870.1 Scope.
870.3 Effective dates of requirement for premarket approval.
870.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Cardiovascular Diagnostic Devices

870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).
870.1100 Blood pressure alarm.
870.1110 Blood pressure computer.
870.1120 Blood pressure cuff.
870.1130 Noninvasive blood pressure measurement system.
870.1140 Venous blood pressure manometer.