§ 868.5115 Premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.


§ 868.5115 Device to relieve acute upper airway obstruction.

(a) Identification. The device is a raised, rounded pad that, in the event of choking on a foreign body, can be applied to the abdomen and pushed upward to generate expulsion pressure to remove the obstruction to relieve acute upper airway obstruction.

(b) Classification. Class II (special controls) (“Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices”). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to § 868.9.

[65 FR 39099, June 23, 2000; 65 FR 47669, Aug. 3, 2000]

§ 868.5120 Anesthesia conduction catheter.

(a) Identification. An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.

(b) Classification. Class II (performance standards).

§ 868.5130 Anesthesia conduction filter.

(a) Identification. An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

(b) Classification. Class II (performance standards).

§ 868.5140 Anesthesia conduction kit.

(a) Identification. An anesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anesthesia. The device may contain syringes, needles, and drugs.

(b) Classification. Class II (performance standards).

§ 868.5150 Anesthesia conduction needle.

(a) Identification. An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

(b) Classification. Class II (performance standards).

§ 868.5160 Gas machine for anesthesia or analgesia.

(a) Gas machine for anesthesia—(1) Identification. A gas machine for anesthesia is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient’s ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.

(2) Classification. Class II (performance standards).

(b) Gas machine for analgesia—(1) Identification. A gas machine for analgesia is a device used to administer to a patient an analgesic agent, such as a nitrous oxide-oxygen mixture (maximum concentration of 70 percent nitrous oxide).

(2) Classification. Class II (performance standards).

§ 868.5165 Nitric oxide administration apparatus.

(a) Identification. The nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.

(b) Classification. Class II. The special control for this device is FDA’s “Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide Analyzer.”

[65 FR 11465, Mar. 3, 2000]

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) Identification. A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient’s laryngotracheal area.

[65 FR 11465, Mar. 3, 2000]