(ii) Technical specifications of the device, including collar sizes, maximum duration of use, operating temperature, and storage temperature range.

(iii) Technical specifications of the vacuum source, including maximum vacuum level and operational vacuum level.

(iv) Instructions for use that includes how to place the device, determination of size, verification of suction, reference to training materials, and information on troubleshooting the device if it does not attach properly.

(v) A warning to screen patients for carotid artery disease due to the probable risk of the device to dislodge arterial plaques in the carotid artery.

(vi) A warning to exclude patients with anatomical abnormalities.

(vii) A warning not to use the device during medical procedures involving medications that contain propofol.

[82 FR 60867, Dec. 26, 2017]

§ 868.5110 Oropharyngeal airway.

(a) *Identification.* An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent 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 the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 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).