

Food and Drug Administration, HHS

§ 868.5115

§ 868.2775 Electrical peripheral nerve stimulator.

(a) *Identification.* An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

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

§ 868.2875 Differential pressure transducer.

(a) *Identification.* A differential pressure transducer is a two-chambered device intended for medical purposes that is often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

(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 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2885 Gas flow transducer.

(a) *Identification.* A gas flow transducer is a device intended for medical purposes that is used to convert gas flow rate into an electrical signal for subsequent display or processing.

(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 1119, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.2900 Gas pressure transducer.

(a) *Identification.* A gas pressure transducer is a device intended for medical purposes that is used to convert gas pressure into an electrical signal for subsequent display or processing.

(b) *Classification.* Class I. The device is exempt from the premarket notification

procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

Subparts D–E [Reserved]

Subpart F—Therapeutic Devices

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device intended to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.

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

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose 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]

§ 868.5110 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