Food and Drug Administration, HHS

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

[51 FR 40388, Nov. 6, 1986, as amended at 66 FR 38795, July 25, 2001]

§ 868.5800 Tracheostomy tube and tube cuff.

(a) Identification. A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient’s aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) Classification. Class II.

[51 FR 40389, Nov. 6, 1986]

§ 868.5810 Airway connector.

(a) Identification. An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.

(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.


§ 868.5820 Dental protector.

(a) Identification. A dental protector is a device intended to protect a patient’s teeth during manipulative procedures within a patient’s oral cavity.

(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.


§ 868.5830 Autotransfusion apparatus.

(a) Identification. An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.

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

§ 868.5860 Pressure tubing and accessories.

(a) Identification. Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.

(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.


§ 868.5870 Nonrebreathing valve.

(a) Identification. A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.

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

§ 868.5880 Anesthetic vaporizer.

(a) Identification. An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

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

§ 868.5895 Continuous ventilator.

(a) Identification. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a pre-determined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

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

§ 868.5905 Noncontinuous ventilator (IPPB).

(a) Identification. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient’s lungs or to assist a patient’s breathing.

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