§ 868.5795 Tracheal tube cleaning brush.
(a) Identification. A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.
(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.

§ 868.5800 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).

§ 868.5840 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.