directly to the lung) in order to isolate a portion of lung distal to the tube.

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

§ 868.5730 **Tracheal tube.**

(a) **Identification.** A tracheal tube is a device inserted into a patient’s trachea via the nose or mouth and used to maintain an open airway.

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

§ 868.5740 **Tracheal/bronchial differential ventilation tube.**

(a) **Identification.** A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.

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

§ 868.5750 **Inflatable tracheal tube cuff.**

(a) **Identification.** An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient’s trachea.

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

§ 868.5760 **Cuff spreader.**

(a) **Identification.** A cuff spreader is a device used to install tracheal tube cuffs on tracheal or tracheostomy tubes.

(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.

§ 868.5770 **Tracheal tube fixation device.**

(a) **Identification.** A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

(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.

§ 868.5780 **Tube introduction forceps.**

(a) **Identification.** Tube introduction forceps (e.g., Magill forceps) are a right-angled device used to grasp a tracheal tube and place it in a patient’s trachea.

(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.

§ 868.5790 **Tracheal tube stylet.**

(a) **Identification.** A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.

(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.

§ 868.5795 **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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180.