§ 868.5830  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, 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 as-
piration of substances, such as blood or vomit, or to provide a means for posi-
tive-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 con-
ector is a device intended to connect
a breathing gas source to a tracheal
tube, tracheostomy tube, or mask.
(b) Classification. Class I (general con-
trols). 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 pa-

tient’s teeth during manipulative pro-
cedures within a patient’s oral cavity.
(b) Classification. Class I (general con-
trols). 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

311