§ 878.3750 Tubular device made of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or tracheal bronchial tree. It may be unbranched or contain one or two branches. The metal tracheal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) Classification. Class II. The special control for this device is FDA’s “Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.”

[65 FR 17146, Mar. 31, 2000]

§ 878.3750 External prosthesis adhesive.

(a) Identification. An external prosthesis adhesive is a silicone-type adhesive intended to be used to fasten to the body an external aesthetic restoration prosthesis, such as an artificial nose.

(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 §878.9.


§ 878.3800 External aesthetic restoration prosthesis.

(a) Identification. An external aesthetic restoration prosthesis is a device intended to be used to construct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.

(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 §878.9.


§ 878.3900 Inflatable extremity splint.

(a) Identification. An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

(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 §878.9.


§ 878.3910 Noninflatable extremity splint.

(a) Identification. A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(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 §878.9. 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 of this chapter, with respect to general requirements concerning records, and §820.198 of this chapter, with respect to complaint files.


§ 878.3925 Plastic surgery kit and accessories.

(a) Identification. A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in...