Food and Drug Administration, HHS

§ 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 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 subpart E of part 807 of this chapter subject to §878.9.