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 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.

Subpart E—Surgical Devices

§ 878.4010 Tissue adhesive.
(a) Tissue adhesive for the topical approximation of skin—(1) Identification. A tissue adhesive for the topical approximation of skin is a device intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for the topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches.
(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: “Tissue Adhesive for the Topical Approximation of Skin.” See §878.1(e) of this chapter for the availability of this guidance document.

§ 878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.
(a) Identification. A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations.