

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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

**§ 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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

**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.

(2) *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.

(b) *Tissue adhesive for non-topical use—(1) Identification.* A tissue adhesive for non-topical use, including adhesives intended for use in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery, is a de-

vice used for adhesion of internal tissues and vessels.

(2) *Classification.* Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3 of this chapter.

[73 FR 31033, May 30, 2008]

**§ 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. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin." See § 878.1(e) for the availability of this guidance document.

[75 FR 68794, Nov. 10, 2010]

**§ 878.4014 Nonresorbable gauze/sponge for external use.**

(a) *Identification.* A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is