

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 device 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]

§ 878.4014 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 composed of materials derived from animal sources.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4015 Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive.

(a) *Identification*. A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2d degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

(b) *Classification*. Class II (special controls). The special control is: the FDA guidance document entitled "Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive." See § 878.1(e) for availability of this guidance document.

[74 FR 53167, Oct. 16, 2009]

§ 878.4018 Hydrophilic wound dressing.

(a) *Identification*. A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

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

§ 878.4020

part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4020 Occlusive wound dressing.

(a) *Identification.* An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4022 Hydrogel wound dressing and burn dressing.

(a) *Identification.* A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a nonresorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. This classification does not include a hydrogel wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended for use in the management of

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closed hyperproliferative (hypertrophic and keloid) scars.

(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.

[69 FR 48148, Aug. 9, 2004]

§ 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I 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 65 FR 2317, Jan. 14, 2000]

§ 878.4100 Organ bag.

(a) *Identification.* An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.

(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 59 FR 63010, Dec. 7, 1994; 65 FR 2318, Jan. 14, 2000]

§ 878.4160 Surgical camera and accessories.

(a) *Identification.* A surgical camera and accessories is a device intended to be used to record operative procedures.

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