

§ 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 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 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

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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. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(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; 83 FR 22848, May 17, 2018]

§ 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

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

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 66 FR 38802, July 25, 2001]

§ 878.4165 Wound autofluorescence imaging device.

(a) *Identification.* A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

(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.

[83 FR 52968, Oct. 19, 2018]

§ 878.4200 Introduction/drainage catheter and accessories.

(a) *Identification.* An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.

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