§ 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.

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

§ 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.

§ 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.

§ 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

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§ 878.4300  Implantable clip.

(a) Identification. An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) Classification. Class II.

§ 878.4320  Removable skin clip.

(a) Identification. A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable.

(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.

§ 878.4340  Contact cooling system for aesthetic use.

(a) Identification. A contact cooling system for aesthetic use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive aesthetic use.

(b) Classification. Class II (special controls). The special controls for this device is FDA’s “Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use.” See §878.1(e) for the availability of this guidance document.

§ 878.4350  Cryosurgical unit and accessories.

(a) Identification—(1) Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories. A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.

(2) Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories. A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.

(b) Classification. Class II.

§ 878.4360  Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.

(a) Identification. A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapeutic agents are used.

(b) Classification—Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

(4) The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

(5) Labeling must include the following: