

## § 878.4495

### § 878.4495 Stainless steel suture.

(a) *Identification.* A stainless steel suture is a needled or unneedled non-absorbable surgical suture composed of 316L stainless steel, in USP sizes 12-0 through 10, or a substantially equivalent stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

(b) *Classification.* Class II (special controls). The device, when it is a steel monofilament suture that is uncoated and does not incorporate barbs, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9. The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

[65 FR 19836, Apr. 13, 2000, as amended at 68 FR 32984, June 3, 2003; 84 FR 71814, Dec. 30, 2019]

### § 878.4520 Polytetrafluoroethylene injectable.

(a) *Identification.* Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* 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.

### § 878.4580 Surgical lamp.

(a) *Identification.* A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) *Classification.* Class II (special controls). The device, when it is an operating room lamp, a surgical instrument light, a surgical floor standing light, an endoscopic surgical light, a surgical light connector, a ceiling mounted surgical light, a surgical light carrier, surgical light accessories, a surgical lamp, a remote illuminator, or an incandescent surgical lamp, is exempt from the premarket notification

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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 84 FR 71814, Dec. 30, 2019]

### § 878.4590 Focused ultrasound stimulator system for aesthetic use.

(a) *Identification.* A Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use." See § 878.1(e) for the availability of this guidance document.

[76 FR 43121, July 20, 2011]

### § 878.4630 Ultraviolet lamp for dermatologic disorders.

(a) *Identification.* An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(b) *Classification.* Class II.

### § 878.4635 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Identification.* A sunlamp product is any device designed to incorporate one or more ultraviolet (UV) lamps intended for irradiation of any part of the living human body, by UV radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning. This definition includes tanning beds and tanning booths. A UV lamp intended for use in sunlamp products is any lamp that produces UV radiation in the wavelength interval of 200 to 400 nanometers in air.

(b) *Classification*. Class II (special controls). The special controls for sunlamp products and UV lamps intended for use in sunlamp products are:

(1) Conduct performance testing that demonstrates the following:

(i) Device meets appropriate output performance specifications such as wavelengths, energy density, and lamp life; and

(ii) Device's safety features, such as timers to limit UV exposure and alarms, function properly.

(2) Demonstrate that device is mechanically safe to prevent user injury.

(3) Demonstrate software verification, validation, and hazard analysis.

(4) Demonstrate that device is biocompatible.

(5) Demonstrate that device is electrically safe and electromagnetically compatible in its intended use environment.

(6) *Labeling*—(i) *Sunlamp products*. (A) The warning statement below must appear on all sunlamp products and must be placed in a black box. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement:

Attention: This sunlamp product should not be used on persons under the age of 18 years.

(B) Manufacturers shall provide validated instructions on cleaning and disinfection of sunlamp products between uses in the user instructions.

(ii) *Sunlamp products and UV lamps intended for use in sunlamp products*. Manufacturers of sunlamp products and UV lamps intended for use in sunlamp

products shall provide or cause to be provided in the user instructions, as well as all consumer-directed catalogs, specification sheets, descriptive brochures, and Web pages in which sunlamp products or UV lamps intended for use in sunlamp products are offered for sale, the following contraindication and warning statements:

(A) “Contraindication: This product is contraindicated for use on persons under the age of 18 years.”

(B) “Contraindication: This product must not be used if skin lesions or open wounds are present.”

(C) “Warning: This product should not be used on individuals who have had skin cancer or have a family history of skin cancer.”

(D) “Warning: Persons repeatedly exposed to UV radiation should be regularly evaluated for skin cancer.”

(c) *Performance standard*. Sunlamp products and UV lamps intended for use in sunlamp products are subject to the electronic product performance standard at § 1040.20 of this chapter.

[79 FR 31213, June 2, 2014]

#### § 878.4660 Skin marker.

(a) *Identification*. A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.

(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 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

#### § 878.4670 Internal tissue marker.

(a) *Identification*. An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.

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

(1) The device must be demonstrated to be biocompatible. Material names