§ 878.4495 Stainless steel suture.

(a) *Identification.* A stainless steel suture is a needled or unneedled nonabsorbable 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 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.