§ 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 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.

[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 photactivate 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 Ultraviolet lamp for tanning.

(a) Identification. An ultraviolet lamp for tanning is a device that is a lamp (including a fixture) intended to provide ultraviolet radiation to tan the skin. See §1040.20 of this chapter.

(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.


§ 878.4660 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.