Food and Drug Administration, HHS

§ 878.4800 Manual surgical instrument for general use.

(a) Identification. A manual surgical instrument for general use is a non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable sutureting

(3) In vivo evaluation must demonstrate performance characteristics of the device, including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

(4) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

(5) Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

(6) The device must be demonstrated to be biocompatible.

(7) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labeling must include identification of compatible introducer needles.

[79 FR 13219, Mar. 10, 2014]

§ 878.4760 Removable skin staple.

(a) Identification. A removable skin staple is a staple-like device intended to connect external 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.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4780 Powered suction pump.

(a) Identification. A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient’s airway or respiratory support system. The device may be used during surgery in the operating room or at the patient’s bedside. The device may include a microbial filter.

(b) Classification. Class II.

§ 878.4790 Powered surgical instrument for improvement in the appearance of cellulite.

(a) Identification. A powered surgical instrument for improvement in the appearance of cellulite is a prescription device that is used for the controlled release of subcutaneous tissue for improvement in the appearance of cellulite. The device consists of a cutting tool powered by a motor and a means for instrument guidance to control the areas of subcutaneous tissue cutting underneath the cellulite depressions or dimples.

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

(1) Non-clinical testing must be performed to demonstrate that the device meets all design specifications and performance requirements, and to demonstrate durability and mechanical integrity of the device.

(2) In vivo evaluation of the device must demonstrate device performance, including the safety of the release methodology and blood loss at the treatment sites.

(3) All elements of the device that may contact the patient must be demonstrated to be biocompatible.

(4) Electrical safety and electromagnetic compatibility of the device must be demonstrated.

(5) The labeling must include a summary of in vivo evaluation data and all the device specific warnings, precautions, and/or contraindications.

(6) Sterility and shelf-life testing for the device must demonstrate the sterility of patient contacting components and the shelf life of these components.

[79 FR 31861, June 3, 2014]
needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

(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.


§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) **Identification.** (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.

(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) **Classification.** (1) Class II.

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §878.9.


§ 878.4820 Surgical instrument motors and accessories/attachments.

(a) **Identification.** Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.

(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.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2318, 2000]

§ 878.4830 Absorbable surgical gut suture.

(a) **Identification.** An absorbable surgical gut suture, both plain and chromic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.

(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.


§ 878.4840 Absorbable polydioxanone surgical suture.

(a) **Identification.** An absorbable polydioxanone surgical suture is an absorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly (p-dioxanone) and is intended for use in soft tissue approximation, including pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. It may be coated or uncoated, undyed or dyed, and with or without a standard needle attached.

(b) **Classification.** Class II (special controls). The special control for the 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.

[67 FR 77676, Dec. 19, 2002]

§ 878.4930 Suture retention device.

(a) **Identification.** A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.