§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) Identification. A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

(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.

§ 878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.

(a) Identification. A non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps, and grafts.

(b) Classification. Class II (special controls). The special controls for this device are FDA’s “Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT).” See §878.1(e) for the availability of this guidance document.

§ 878.4700 Surgical microscope and accessories.

(a) Identification. A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(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.

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) Identification. A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.

(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.

§ 878.4750 Implantable staple.

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

(b) Classification. Class II.

§ 878.4755 Absorbable lung biopsy plug.

(a) Identification. A preformed (polymerized) absorbable lung biopsy plug is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

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

1. The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

2. Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.
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§ 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.

§ 878.4770 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.

§ 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 applicer, 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 suturing needle.