through which nutritional formula is directed. The device fits in line with enteral feeding systems.

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

(1) The patient contacting components of the device must be demonstrated to be biocompatible.

(2) *In vivo* testing must be performed and must demonstrate that the device causes neither an adverse tissue response nor adverse performance.

(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mechanical testing to demonstrate that the device can withstand clinical forces;

(ii) Flow rate and leakage testing to demonstrate that the device does not impede the flow of enteral formula;

(iii) Demonstration of enzymatic effect on intended macronutrient;

(iv) The amount of enzyme that exits the cartridge must be characterized;

(v) Validation that the device does not adversely impact the nutritional composition of enteral formula; and

(vi) Validation that the device does not impede flow alarms on enteral feeding pumps.

(4) Human factors testing must be performed to characterize use error risks.

(5) Performance data must support shelf life by demonstrating package integrity and device functionality over the identified shelf life.

(6) Labeling must include the following:

(i) A detailed summary of *in vivo* testing pertinent to use of the device, including device-related adverse events;

(ii) A detailed summary of compatible formulas that is supported by nonclinical testing, including the expected enzymatic conversion as a percentage;

(iii) Detailed instructions on how to place the device into an enteral feeding circuit;

(iv) A warning regarding the possibility for misconnections; and

(v) Expiration date or shelf life.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, adverse effects, and complications;

(ii) A description of the device and how it operates;

(iii) Instructions on how to correctly use the device; and

(iv) The benefits and risks associated with the use of the device.

[82 FR 47971, Oct. 16, 2017]

§ 876.5990 Extracorporeal shock wave lithotripter.

(a) *Identification.* An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

(b) *Classification.* Class II (special controls) (FDA guidance document: ''Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'')

[65 FR 48612, Aug. 9, 2000]

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

Sec.

Subpart F—Therapeutic Devices

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

SOURCE: 53 FR 23872, June 24, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 878 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a general and plastic surgery device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.*.

[53 FR 23872, June 24, 1988, as amended at 67 FR 77676, Dec. 19, 2002; 78 FR 18233, Mar. 26, 2013]

§ 878.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the

act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(l) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2317, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 878.1800 Speculum and accessories.

(a) *Identification.* A speculum is a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various accessories.

(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 54 FR 13827, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 878.3250 External facial fracture fixation appliance.

(a) *Identification.* An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship.

(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 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

§ 878.3300 Surgical mesh.

(a) *Identification.* Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery.

(b) *Classification.* Class II.

§ 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

(a) *Identification.* A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient's need.

(b) *Classification.* Class II.

§ 878.3510 Carbon dioxide gas controlled tissue expander.

(a) *Identification.* A carbon dioxide gas controlled tissue expander is a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

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

(1) In-vivo performance testing must be conducted to obtain the adverse

event profile associated with use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of patient-contacting components of the device.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Cycle testing of expander showing that there are no leaks or tears after repeated cycling;

(ii) Mechanical assessment of implanted carbon dioxide (CO_2) canister including high impact testing;

(iii) Leak testing of expander showing that device does not leak CO_2;

(iv) Assessment of gas permeability during expansion and after full expansion; and

(v) Mechanical assessment of expander (tensile set, breaking force, shell joint test, and fused or adhered joint testing).

(5) Performance data must be provided to demonstrate the electromagnetic compatibility, electrical safety, and wireless compatibility of the device.

(6) Software verification, validation, and hazard analysis must be performed.

(7) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the identified shelf life.

(8) Human factors testing and analysis must validate that the device design and labeling are sufficient for the end user.

(9) Physician labeling must include:

(i) The operating parameters, name, and model number of the indicated external dosage controller;

(ii) Information on how the device operates and the typical course of treatment;

(iii) Information on the population for which the device has been demonstrated to be effective;

(iv) A detailed summary of the device technical parameters; and

(v) Provisions for choosing an appropriate size implant that would be exchanged for the tissue expander.

(10) Patient labeling must include:

(i) Warnings, precautions, and contraindications, and adverse events/complications;

(ii) Information on how the device operates and the typical course of treatment;

(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-operative care instructions; and

(v) Alternative treatments.

(11) Patient training must include instructions for device use, when it may be necessary to contact a physician, and cautionary measures to take when the device is implanted.

[87 FR 6421, Feb. 4, 2022]

§ 878.3530 Silicone inflatable breast prosthesis.

(a) *Identification.* A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before November 17, 1999, been found to be substantially equivalent to a silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone inflatable breast prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[53 FR 23872, June 24, 1988, as amended at 64 FR 45161, Aug. 19, 1999]

§ 878.3540 Silicone gel-filled breast prosthesis.

(a) *Identification*—(1) *Single-lumen silicone gel-filled breast prosthesis.* A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(2) *Double-lumen silicone gel-filled breast prosthesis.* A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(3) *Polyurethane covered silicone gel-filled breast prosthesis.* A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification.* Class III.

(c) *Date premarket approval application (PMA) is required.* A PMA is required to be filed with the Food and Drug Administration on or before July 9, 1991 for any silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 9, 1991 been found to be substantially equivalent to a silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone gel-filled breast prosthesis shall have an approved PMA in effect before being placed in commercial distribution.

[53 FR 23872, June 24, 1988, as amended at 56 FR 14627, Apr. 10, 1991]

§ 878.3550 Chin prosthesis.

(a) *Identification.* A chin prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the chin.

(b) *Classification.* Class II.

§ 878.3590 Ear prosthesis.

(a) *Identification.* An ear prosthesis is a silicone rubber solid device intended to be implanted to reconstruct the external ear.

(b) *Classification.* Class II.

§ 878.3610 Esophageal prosthesis.

(a) *Identification.* An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.''

[65 FR 17145, Mar. 31, 2000]

§ 878.3680 Nose prosthesis.

(a) *Identification.* A nose prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the nasal dorsum.

(b) *Classification.* Class II.

§ 878.3720 Tracheal prosthesis.

(a) *Identification.* The tracheal prosthesis is a rigid, flexible, or expandable tubular device made of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree. It may be unbranched or contain one or two branches. The metal tracheal prosthesis may be uncovered or covered

with a polymeric material. This device may also include a device delivery system.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.''

[65 FR 17146, Mar. 31, 2000]

§ 878.3750 External prosthesis adhesive.

(a) *Identification.* An external prosthesis adhesive is a silicone-type adhesive intended to be used to fasten to the body an external aesthetic restoration prosthesis, such as an artificial nose.

(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 38802, July 25, 2001]

§ 878.3800 External aesthetic restoration prosthesis.

(a) *Identification.* An external aesthetic restoration prosthesis is a device intended to be used to construct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.

(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. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

§ 878.3900 Inflatable extremity splint.

(a) *Identification.* An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

(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 38802, July 25, 2001]

§ 878.3910 Noninflatable extremity splint.

(a) *Identification.* A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

§ 878.3925 Plastic surgery kit and accessories.

(a) *Identification.* A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(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 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

Subpart E—Surgical Devices

§ 878.4010 Tissue adhesive.

(a) *Tissue adhesive for the topical approximation of skin*—(1) *Identification.* A tissue adhesive for the topical approximation of skin is a device intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for the topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: ''Tissue Adhesive for the Topical Approximation of Skin.'' See § 878.1(e) of this chapter for the availability of this guidance document.

(b) *Tissue adhesive for non-topical use*—(1) *Identification.* A tissue adhesive for non-topical use, including adhesives intended for use in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery, is a device used for adhesion of internal tissues and vessels.

(2) *Classification.* Class III (premarket approval). 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 of this chapter.

[73 FR 31033, May 30, 2008]

§ 878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.

(a) *Identification.* A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin.'' See § 878.1(e) for the availability of this guidance document.

[75 FR 68794, Nov. 10, 2010]

§ 878.4014 Nonresorbable gauze/sponge for external use.

(a) *Identification.* A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4015 Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive.

(a) *Identification.* A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2d degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

(b) *Classification.* Class II (special controls). The special control is: the FDA guidance document entitled ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive.'' See § 878.1(e) for availability of this guidance document.

[74 FR 53167, Oct. 16, 2009]

§ 878.4018 Hydrophilic wound dressing.

(a) *Identification.* A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4020 Occlusive wound dressing.

(a) *Identification.* An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4022 Hydrogel wound dressing and burn dressing.

(a) *Identification.* A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a nonresorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. This classification does not include a hydrogel wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in § 878.9.

[64 FR 53929, Oct. 5, 1999]

§ 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

(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.

[69 FR 48148, Aug. 9, 2004]

§ 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill

microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I 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 2317, Jan. 14, 2000; 83 FR 22848, May 17, 2018]

§ 878.4100 Organ bag.

(a) *Identification.* An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.

(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 59 FR 63010, Dec. 7, 1994; 65 FR 2318, Jan. 14, 2000]

§ 878.4160 Surgical camera and accessories.

(a) *Identification.* A surgical camera and accessories is a device intended to be used to record operative procedures.

(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 54 FR 13827, Apr. 5, 1989; 66 FR 38802, July 25, 2001]

§ 878.4165 Wound autofluorescence imaging device.

(a) *Identification.* A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

(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.

[83 FR 52968, Oct. 19, 2018]

§ 878.4200 Introduction/drainage catheter and accessories.

(a) *Identification.* An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.

(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]

§ 878.4300 Implantable clip.

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

(b) *Classification.* Class II.

§ 878.4320 Removable skin clip.

(a) *Identification.* A removable skin clip is a clip-like device intended to connect skin 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]

§ 878.4340 Contact cooling system for aesthetic use.

(a) *Identification.* A contact cooling system for aesthetic use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive aesthetic use.

(b) *Classification.* Class II (special controls). The special controls for this device is FDA's ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use.'' See § 878.1(e) for the availability of this guidance document.

[76 FR 6553, Feb. 7, 2011]

§ 878.4350 Cryosurgical unit and accessories.

(a) *Identification*—(1) *Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories.* A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.

(2) *Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories.* A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.

(3) *Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories.* A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.

(b) *Classification.* Class II.

§ 878.4360 Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.

(a) *Identification.* A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

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

(1) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

(4) The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

(5) Labeling must include the following:

(i) A statement describing the potential risk of developing scalp metastasis.

(ii) Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

(iii) A summary of the non-clinical and/or clinical testing pertinent to use of the device.

(iv) A summary of the device technical parameters, including temperature cooling range and duration of cooling.

(v) A summary of the device- and procedure-related adverse events pertinent to use of the device.

(vi) Information on how the device operates and the typical course of treatment.

(6) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse effects/complications.

(ii) Information on how the device operates and the typical course of treatment.

(iii) Information on the patient population for which there is clinical evidence of effectiveness.

(iv) The potential risks and benefits associated with use of the device.

(v) Postoperative care instructions.

(vi) A statement describing the potential risk of developing scalp metastasis.

[81 FR 7453, Feb. 12, 2016]

§ 878.4370 Surgical drape and drape accessories.

(a) *Identification.* A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy.

(b) *Classification.* Class II (special controls). The device, when it is an ear, nose, and throat surgical drape, a latex sheet drape with self-retaining finger cot, a disposable urological drape, a Kelly pad, an ophthalmic patient drape, an ophthalmic microscope drape, an internal drape retention ring (wound protector), or a surgical drape that does not include an antimicrobial agent, 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]

§ 878.4371 Irrigating wound retractor device.

(a) *Identification.* An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible and evaluated for particulate matter.

(2) Performance data must demonstrate the sterility and pyrogenicity of the patient-contacting components of the device.

(3) Performance data must support shelf life by demonstrating continued functionality and sterility of the device over the identified shelf life.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must:

(i) Characterize the tear resistance, tensile strength, and elongation properties of the barrier material;

(ii) Demonstrate that the liquid barrier material is resistant to penetration by blood, and is non-flammable;

(iii) Characterize the forces required to deploy the device;

(iv) Characterize the device's ranges of operation, including flow rates and maximum suction pressures;

(v) Demonstrate the ability of the device irrigation apparatus to maintain a user defined or preset flow rate to the surgical wound; and

(vi) Demonstrate the ability of the device to maintain user defined or preset removal rates of fluid from the surgical wound.

(5) The labeling must include or state the following information:

(i) Device size or incision length range;

(ii) Method of sterilization;

(iii) Flammability classification;

(iv) Non-pyrogenic;

(v) Shelf life; and

(vi) Maximum flow rate and suction pressure.

[83 FR 24, Jan. 2, 2018]

§ 878.4380 Drape adhesive.

(a) *Identification.* A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.

(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 38802, July 25, 2001]

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) *Identification.* An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(b) *Classification.* Class II.

§ 878.4410 Low energy ultrasound wound cleaner.

(a) *Identification.* A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.'' See § 878.1(e) for the availability of this guidance document.

[70 FR 67355, Nov. 7, 2005]

§ 878.4420 Electrosurgical device for over-the-counter aesthetic use.

(a) *Identification.* An electrosurgical device for over-the-counter aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.

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

(1) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested: Over-heating, power accuracy radiofrequency, pulse cycle, waveform, pulse duration, and device characterization parameters.

(2) Label comprehension and self-selection performance evaluation must demonstrate that the intended over-the-counter users can understand the package labeling and correctly choose the device for the indicated aesthetic use.

(3) Usability performance evaluation must demonstrate that the over-the-counter user can correctly use the device, based solely on reading the directions for use, to treat the indicated aesthetic use.

(4) Clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use to achieve the intended aesthetic results.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Instructions for cleaning the device must be validated.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety, including the mechanical integrity, of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include:

(i) Warnings, precautions, and contraindications to ensure the safe use of the device for the over-the-counter users.

(ii) A statement that the safety and effectiveness of the device's use for uses other than the indicated aesthetic use are not known.

(iii) A summary of the clinical information used to establish effectiveness for each indicated aesthetic usage and observed adverse events.

[81 FR 42244, June 29, 2016]

§ 878.4430 Microneedling device for aesthetic use.

(a) *Identification.* A microneedling device for aesthetic use is a device using one or more needles to mechanically

puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

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

(1) The technical specifications and needle characteristics must be identified, including needle length, geometry, maximum penetration depth, and puncture rate.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Accuracy of needle penetration depth and puncture rate;

(ii) Safety features built into the device to protect against cross-contamination, including fluid ingress protection; and

(iii) Identification of the maximum safe needle penetration depth for the device for the labeled indications for use.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

(5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.

(6) Software verification, validation, and hazard analysis must be performed for all software components of the device.

(7) The patient-contacting components of the device must be demonstrated to be biocompatible.

(8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.

(9) Labeling must include the following:

(i) Information on how to operate the device and its components and the typical course of treatment;

(ii) A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;

(iii) Validated methods and instructions for reprocessing of any reusable components;

(iv) Disposal instructions; and

(v) A shelf life.

(10) Patient labeling must be provided and must include:

(i) Information on how the device operates and the typical course of treatment;

(ii) The probable risks and benefits associated with use of the device; and

(iii) Postoperative care instructions.

[83 FR 26577, June 8, 2018]

§ 878.4440 Eye pad.

(a) *Identification.* An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.

(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]

§ 878.4450 Nonabsorbable gauze for internal use.

(a) *Identification.* Nonabsorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.

(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 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 878.4452 Nonabsorbable expandable hemostatic sponge for temporary internal use.

(a) *Identification.* A nonabsorbable expandable hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, nonabsorbable radiopaque compressed sponges and may include an applicator to facilitate delivery into a wound.

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

(1) Performance data must demonstrate the biocompatibility of patient-contacting components.

(2) Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.

(3) Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.

(4) Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:

(i) Material specifications.

(ii) Immunogenicity.

(iii) Viral inactivation for animal-derived materials.

(5) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Absorption capacity.

(ii) Extent of swelling.

(iii) Mechanical properties.

(iv) Expansion force/pressure.

(v) Radiopacity.

(vi) Deployment/applicator functionality.

(6) In vivo performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: Controls bleeding, does not promote adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:

(i) Deployment.

(ii) Control of bleeding.

(iii) Radiopacity.

(iv) Retrieval.

(v) Assessment of local and systemic effects.

(7) Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.

(8) Labeling must include:

(i) Specific instructions for deployment by emergency responders and retrieval by surgeons.

(ii) Warnings, cautions, and limitations needed for safe use of the device.

(iii) Information on how the device operates and the typical course of treatment.

(iv) A detailed summary of the in vivo and human factors testing pertinent to use of the device.

(v) Appropriate imaging information to ensure complete retrieval of device.

(vi) An expiration date/shelf life.

[79 FR 34224, June 16, 2014]

§ 878.4454 Non-absorbable, hemostatic gauze for temporary internal use.

(a) *Identification.* A non-absorbable, hemostatic gauze for temporary internal use is a prescription device intended to be placed temporarily for control of severely bleeding wounds such as surgical wounds and traumatic injuries. The gauze is coated or impregnated with a hemostatic material which may enhance hemostasis by physical means. The device is intended to be removed once the patient is stabilized.

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

(1) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Specifically testing must:
(i) Demonstrate that the device is able to achieve hemostasis;
(ii) Demonstrate that the device can be radiographically detected; and
(iii) Assess pertinent safety endpoints including vascular obstruction and adhesion formation.
(2) The device must be demonstrated to be biocompatible.
(3) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following tests must be performed:
(i) In vitro clot assessment;
(ii) Particulate release testing;
(iii) Physical characterization, including swelling percent and particulate size;
(iv) Chemical characterization;
(v) Radiopacity testing; and
(vi) Mechanical integrity testing, including tensile strength and tear strength.
(4) Performance data must demonstrate the sterility of the device.
(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
(6) Labeling must include the following:
(i) Instructions for use, including an instruction to remove all visible device components by irrigation;
(ii) The maximum amount of time the device may be left within the body;
(iii) A shelf life;
(iv) A contraindication for intravascular use of the device; and
(v) A warning regarding the potential for adhesion formation.

[83 FR 6794, Feb. 15, 2018]

§ 878.4456 Hemostatic device for intraluminal gastrointestinal use.

(a) *Identification.* A hemostatic device for intraluminal gastrointestinal use is a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or by other physical means.

(b) *Classification.* Class II (special controls). The special controls for this device are:
(1) The device must be demonstrated to be biocompatible.
(2) Performance data must support the sterility and pyrogenicity of the device.
(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
(4) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The testing must evaluate the following:
(i) The ability to deliver the hemostatic material to the bleeding site;
(ii) The ability to achieve hemostasis in a clinically relevant model of gastrointestinal bleeding; and
(iii) Safety endpoints, including thromboembolic events, local and systemic toxicity, tissue trauma, gastrointestinal tract obstruction, and bowel distension and perforation.
(5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
(i) Materials characterization of all components must demonstrate the device meets established specifications, which must include compositional identity and purity, characterization of impurities, physical characteristics, and reactivity with fluids.
(ii) Performance testing must demonstrate the mechanical integrity and functionality of the system used to deliver the device and demonstrate the device meets established specifications, including output pressure for propellant-based systems.
(6) Labeling must include:
(i) Information identifying and explaining how to use the device and its components; and
(ii) A shelf life.

[83 FR 52971, Oct. 19, 2018]

§ 878.4460 Non-powdered surgeon's glove.

(a) *Identification.* A non-powdered surgeon's glove is a device intended to be

worn on the hands of operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

(b) *Classification.* Class I (general controls).

[53 FR 23872, June 24, 1988, as amended at 66 FR 46952, Sept. 10, 2001; 81 FR 91730, Dec. 19, 2016]

§ 878.4470 Surgeon's gloving cream.

(a) *Identification.* Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.

(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]

§ 878.4490 Absorbable hemostatic agent and dressing.

(a) *Identification.* An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.

(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.

§ 878.4493 Absorbable poly(glycolide/l-lactide) surgical suture.

(a) *Identification.* An absorbable poly(glycolide/l-lactide) surgical suture (PGL suture) is an absorbable sterile, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percent l-lactide, and is indicated for use in soft tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. ''Monograph for Absorbable Surgical Sutures;'' it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.

(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.

[56 FR 47151, Sept. 18, 1991, as amended at 68 FR 32984, June 3, 2003]

§ 878.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

(a) *Identification.* An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant deoxyribonucleic acid (DNA) technology. The device is intended for use in general soft tissue approximation and ligation.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.'' For the availability of this guidance document see § 878.1(e).

[72 FR 43146, Aug. 3, 2007]

§ 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.

§ 878.4550 Autofluorescence detection device for general surgery and dermatological use.

(a) *Identification.* An autofluorescence detection device for general surgery and dermatological use is an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

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

(1) In vivo testing under anticipated conditions of use must characterize the ability of the device to detect autofluorescent signals from tissues or structures consistent with the indications for use.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(6) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(7) Performance testing must demonstrate laser and light safety for eye, tissue, and skin.

(8) Labeling must include the following:

(i) Instructions for use;

(ii) The detection performance characteristics of the device when used as intended; and

(iii) A shelf life for any sterile components.

[87 FR 24273, Apr. 25, 2022]

§ 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.

(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 and specific designation numbers must be provided.

(2) Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.

(3) Performance data must demonstrate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating sterility, package integrity, device functionality, and material stability over the requested shelf life.

(5) Labeling must include:

(i) A warning that the device must not be used on a non-sterile surface prior to use internally.

(ii) An expiration date/shelf life.

(iii) Single use only labeling must be labeled directly on the device.

[80 FR 46486, Aug. 5, 2015]

§ 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.

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

§ 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 control for this device is 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.

[75 FR 70114, Nov. 17, 2010]

§ 878.4685 Extracorporeal shock wave device for treatment of chronic wounds.

(a) *Identification.* An extracorporeal shock wave device for treatment of chronic wounds is a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and transferred to the body using an acoustic interface.

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

(1) Non-clinical performance testing must be conducted to demonstrate that the system produces anticipated and reproducible acoustic pressure shock waves.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate that the reusable components of the device can be reprocessed for subsequent use.

(4) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must support the use life of the system by demonstrating continued system functionality over the labeled use life.

(7) Physician labeling must include:

(i) Information on how the device operates and the typical course of treatment;

(ii) A detailed summary of the device's technical parameters;

(iii) Validated methods and instructions for reprocessing of any reusable components; and

(iv) Instructions for preventing hearing loss by use of hearing protection.

(8) Patient labeling must include:

(i) Relevant contraindications, warnings, precautions, adverse effects, and complications;

(ii) Information on how the device operates and the typical course of treatment;

(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-procedure care instructions; and

(v) Alternative treatments.

[83 FR 9699, Mar. 7, 2018]

§ 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.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 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.

[53 FR 23872, June 24, 1988, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4740 Surgical stapler.

(a) Surgical stapler for external use.

(1) *Identification.* A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery.

(2) *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.

(b) Surgical stapler for internal use.

(1) *Identification.* A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses.

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

(i) Performance testing must demonstrate that the stapler, when used with compatible staples, performs as intended under anticipated conditions of use. Performance testing must include the following:

(A) Evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type;

(B) For manual staplers only, measurement of the worst-case deployment pressures on stapler firing force;

(C) Measurement of staple line strength;

(D) Confirmation of staple line integrity; and

(E) In vivo confirmation of staple line hemostasis.

(ii) For powered staplers only, appropriate analysis/testing must demonstrate the electromagnetic compatibility and electrical, thermal, and mechanical safety of the device.

(iii) For powered staplers only, appropriate software verification, validation, and hazard analysis must be performed.

(iv) Human factors testing must demonstrate that the clinician can correctly select and safely use the device,

as identified in the labeling, based on reading the directions for use.

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

(vi) Performance data must demonstrate the sterility of the device.

(vii) Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

(viii) Performance data must support the shelf life of the device by demonstrating continued device functionality, sterility, and package integrity over the identified shelf life.

(ix) Labeling of the device must include the following:

(A) Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of tissues that are necrotic, friable, or have altered integrity.

(B) Unless available information demonstrates that the specific warnings do not apply, the labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use including:

(*1*) Avoidance of use of the stapler to staple tissue outside of the labeled limits for maximum and minimum tissue thickness;

(*2*) Avoidance of obstructions to the creation of the staple line and the unintended stapling of other anatomic structures;

(*3*) Avoidance of clamping and unclamping of delicate tissue structures to prevent tissue damage;

(*4*) Avoidance of use of the stapler on the aorta;

(*5*) Establishing proximal control of blood vessels prior to stapling where practical and methods of blood vessel control in the event of stapler failure;

(*6*) Ensuring stapler compatibility with staples; and

(*7*) Risks specifically associated with the crossing of staple lines.

(C) Specific user instructions for proper device use including measures associated with the prevention of device malfunction, and evaluation of the appropriateness of the target tissue for stapling.

(D) List of staples with which the stapler has been demonstrated to be compatible.

(E) Identification of key performance parameters and technical characteristics of the stapler and the compatible staples needed for safe use of the device.

(F) Information regarding tissues on which the stapler is intended to be used.

(G) Identification of safety mechanisms of the stapler.

(H) Validated methods and instructions for reprocessing of any reusable device components.

(I) An expiration date/shelf life.

(x) Package labels must include critical information and technical characteristics necessary for proper device selection.

[86 FR 16204, Oct. 8, 2021]

§ 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.

(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.

§ 878.4783 Negative pressure wound therapy device for reduction of wound complications.

(a) *Identification.* A negative pressure wound therapy device for reduction of wound complications is a powered suction pump intended for wound management and reduction of wound complications via application of negative pressure to the wound, which removes fluids, including wound exudate, irrigation fluids, and infectious materials. This device type is intended for use with wound dressings classified under § 878.4780. This classification does not include devices intended for organ space wounds.

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

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the following:

(i) Wound complication rates; and

(ii) All adverse events.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(5) Usability testing must demonstrate that intended users can correctly use the device, based solely on reading the instructions for use.

(6) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested in a worst-case scenario for the intended use life:

(i) Ability to maintain pressure levels at the wound site under a worst-case scenario for the intended use life;

(ii) Fluid removal rate consistent with the wound types specified in the indications for use; and

(iii) Timely triggering of all alarms.

(7) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include the following:

(i) Instructions for use;

(ii) A summary of the device technical specifications, including pressure settings, modes (*e.g.*, continuous or intermittent), alarms, and safety features;

(iii) Compatible components and devices;

(iv) A summary of the clinical evidence for the indications for use;

(v) A shelf life for sterile components; and

(vi) Use life and intended use environments.

(10) For devices intended for use outside of a healthcare facility, patient labeling must include the following:

(i) Information on how to operate the device and its components and the typical course of treatment;

(ii) Information on when to contact a healthcare professional; and

(iii) Use life.

[86 FR 70734, Dec. 10, 2021]

§ 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]

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, 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, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing 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 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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001; 86 FR 56204, Oct. 8, 2021; 86 FR 66188, Nov. 22, 2021]

§ 878.4805 Manual percutaneous surgical set assembled in the abdomen.

(a) *Identification.* A manual percutaneous surgical set assembled in the abdomen is a prescription device consisting of a percutaneous surgical set used as a means to penetrate soft

tissue to access certain areas of the abdomen. The device's effectors or attachments are provided separately from the percutaneous shaft and are introduced to the site via a traditional conduit such as a trocar. The attachment or effectors are connected to the shaft once the tip of the shaft is inside the abdomen. Once inside the abdomen, the surgical set is used to grasp, hold, and manipulate soft tissues. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Dimensional verification testing must be conducted.

(ii) Force verification testing must be conducted. The force testing must demonstrate the forces necessary to insert and operate each component of the device during use as intended.

(iii) Functional verification testing of the device components must be conducted.

(5) Simulated use testing in an anatomically relevant animal model must demonstrate the device's ability to penetrate soft tissue, be assembled in situ, and to grasp, hold and manipulate soft tissues in the intended treatment area.

(6) The labeling must include the following:

(i) Instructions for use, including detailed instructions for instrument assembly, disassembly, and removal; and

(ii) A shelf life.

[86 FR 71569, Dec. 17, 2021]

§ 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.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 878.4815 Magnetic surgical instrument system.

(a) *Identification.* A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

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

(1) In vivo performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

(2) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Magnetic field strength testing characterization to identify the distances from the magnet that are safe

for patients and users with ferromagnetic implants, devices, or objects.

(ii) Ability of the internal surgical instrument(s) to be coupled, de-coupled, and re-coupled with the external magnet over the external magnet use life.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that are patient-contacting.

(5) Methods and instructions for reprocessing reusable components must be validated.

(6) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components and device functionality over the labeled shelf life.

(7) Training must be developed and validated by human factors testing and analysis to ensure users can follow the instructions for use to allow safe use of the device.

(8) Labeling must include:

(i) Magnetic field safe zones.

(ii) Instructions for proper device use.

(iii) A screening checklist to ensure that all patients and operating staff are screened from bringing ferromagnetic implants, devices, or objects near the external magnet.

(iv) Reprocessing instructions for any reusable components.

(v) Shelf life.

(vi) Use life.

[81 FR 64763, Sept. 21, 2016]

§ 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]

§ 878.4825 General laparoscopic power morcellation containment system.

(a) *Identification.* A general laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

(4) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion/withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that compatible laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that users can adequately deploy the device,

morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents.

(5) Training must be developed and validated to ensure users can follow the instructions for use.

(6) Labeling must include:

(i) A contraindication for use in gynecological procedures;

(ii) A contraindication against use of tissue that is known or suspected to contain malignancy;

(iii) The following boxed warning: ''Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk;''

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) A shelf life.

[86 FR 66458, Nov. 23, 2021]

§ 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.

[54 FR 50738, Dec. 11, 1989, as amended at 68 FR 32984, June 3, 2003]

§ 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]

§ 878.4850 Blood lancets.

(a) *Single use only blood lancet with an integral sharps injury prevention feature*—(1) *Identification.* A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and must include a sharps injury prevention feature.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use and that the integral sharps injury prevention feature will irreversibly disable the device after one use.

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

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device and its sharps injury prevention feature.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Discard the entire device after use.''

(B) ''Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.''

(b) *Single use only blood lancet without an integral sharps injury prevention feature*—(1) *Identification.* A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

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

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Discard the entire device after use.''

(B) ''Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.''

(c) *Multiple use blood lancet for single patient use only*—(1) *Identification.* A multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that:

(A) The lancet blade can be changed with every use, either manually or by triggering a blade storage unit to discard the used blade and reload an unused blade into the reusable base; and

(B) The structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions and allow for validated cleaning and disinfection.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use.

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

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Validation testing must demonstrate that the cleaning and disinfection instructions are adequate to ensure that the reusable lancet base can be cleaned and low level disinfected.

(vi) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) The Environmental Protection Agency (EPA) registered disinfectant's contact time for disinfectant use.

(C) Handwashing instructions for the user before and after use of the device.

(D) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(E) Instructions on the cleaning and disinfection of the device.

(F) Instructions for the safe disposal of the device.

(G) Instructions for use must address the safe storage of the reusable blood lancet base between uses to minimize contamination or damage and the safe storage and disposal of the refill lancet blades.

(H) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vii) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.''

(B) ''Used lancet blades must be safely discarded after a single use.''

(C) ''Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.''

(d) *Multiple use blood lancet for multiple patient use*—(1) *Identification.* A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class III (premarket approval).

(3) *Date PMA or notice of completion of a PDP is required:* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 22, 2024, for any multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before May 22, 2024, been found to be substantially equivalent to a multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976. Any other multiple use blood lancet for multiple patient use shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[86 FR 66188, Nov. 22, 2021, as amended at 86 FR 66179, Nov. 22, 2021]

§ 878.4860 Light based energy source device for topical application.

(a) *Identification.* The device emits light energy at near infrared spectrum and is applied externally to the surface of herpes simplex labialis lesions on or around the lips.

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

(1) The technical parameters of the device, including wavelength, treatment time, treatment area, energy density, spot size, and power, must be characterized.

(2) The cleaning and disinfection instructions for the device must be validated.

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

(4) Performance testing must validate electromagnetic compatibility (EMC), ocular safety, and electrical safety of the device.

(5) Labeling must direct end-users to contact the device manufacturer and MedWatch if they experience any adverse events when using this device.

(6) Labeling must include specific information pertinent to use of the device by the intended patient population and the treatment regimen.

(7) Simulated use testing must include information from a usability, label comprehension and self-selection study to demonstrate that the device can be used by the intended patient population without any assistance.

(8) Clinical data must show adequate reduction in time to healing and assess risks of redness, discomfort, burns, and blisters.

[83 FR 52969, Oct. 19, 2018]

§ 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.

(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]

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(a) *Identification.* A manual operating table and accessories and a manual operating chair and accessories are nonpowered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.

(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 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4960 Operating tables and accessories and operating chairs and accessories.

(a) *Identification.* Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.

(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, Jan. 14, 2000]

§ 878.4961 Mountable electromechanical surgical system for transluminal approaches.

(a) *Identification.* A mountable electromechanical surgical system for transluminal approaches is a software-controlled, patient bed- and/or operating table-mounted electromechanical surgical system with human/device interfaces that allows a qualified user to perform transluminal endoscopic or laparoscopic surgical procedures using surgical instruments attached to an electromechanical arm.

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

(1) The device manufacturer must develop, and update as necessary, a device-specific use training program that ensures proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error.

(2) The device manufacturer may only distribute the device to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program.

(3) The device manufacturer must conduct and complete post-market surveillance, including an impact of the training program on user learning, behavior, and performance, in accordance with an FDA-agreed-upon protocol.

The device manufacturer must submit post-market surveillance reports that contain current data and findings in accordance with the FDA-agreed-upon protocol.

(4) The device manufacturer must submit a report to FDA annually on the anniversary of initial marketing authorization for the device, until such time as FDA may terminate such reporting, which comprises the following information:

(i) Cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization; and

(ii) Identification and rationale for changes made to the device, labeling or device-specific use training program, which did not require submission of a premarket notification during the reporting period.

(5) Labeling must include:

(i) A detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;

(ii) A statement in the labeling that the safety and effectiveness of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (b)(3) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (b)(3) of this section.

(6) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.

(7) Human factors validation testing must be performed and must demonstrate that the user interfaces of the system support safe use in an operating room environment.

(8) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

(i) Device motion accuracy and precision;

(ii) System testing;

(iii) Instrument reliability;

(iv) Thermal effects on tissue;

(v) Human-device interface;

(vi) Mounting hardware testing;

(vii) Workspace access testing; and

(viii) Performance testing with compatible devices.

(9) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users/patients as part of cybersecurity review.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

(13) Performance data must validate the reprocessing instructions for the reusable components of the device.

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting

components of the device are nonpyrogenic.

[87 FR 26995, May 6, 2022]

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) *Identification.* Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(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.

[56 FR 24685, May 31, 1991, as amended at 68 FR 32984, June 3, 2003]

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) *Identification.* Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

(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.

[56 FR 24685, May 31, 1991, as amended at 68 FR 32984, June 3, 2003]

§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) *Identification.* Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation. The polyamide surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it may be monofilament or multifilament in form; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(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.

[56 FR 24685, May 31, 1991, as amended at 68 FR 32985, June 3, 2003]

§ 878.5030 Natural nonabsorbable silk surgical suture.

(a) *Identification.* Natural nonabsorbable silk surgical suture is a nonabsorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori* (*B. mori*) of the family *Bombycidae.* Natural nonabsorbable silk surgical suture is indicated for use in soft tissue approximation. Natural nonabsorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for Nonabsorbable Surgical Suture (class I). Natural nonabsorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive.

(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.

[58 FR 57558, Oct. 26, 1993, as amended at 68 FR 32985, June 3, 2003]

§ 878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

(a) *Identification.* Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

(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.

[65 FR 20735, Apr. 18, 2000, as amended at 68 FR 32985, June 3, 2003]

§ 878.5040 Suction lipoplasty system.

(a) *Identification.* A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of ⅓ horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

(b) *Classification.* Class II (special controls). Consensus standards and labeling restrictions.

[63 FR 7705, Feb. 17, 1998]

§ 878.5050 Surgical smoke precipitator.

(a) *Identification.* A surgical smoke precipitator is a prescription device intended for clearance of the visual field by precipitation of surgical smoke and other aerosolized particulate matter created during laparoscopic surgery.

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

(1) Adverse tissue reaction must be mitigated through the following:

(i) Chemical characterization and toxicological risk assessment of the treated surgical smoke.

(ii) Demonstration that the elements of the device that may contact the patient are biocompatible.

(2) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Performance data must demonstrate the sterility of the patient contacting components of the device.

(5) Performance data must support the shelf life of the sterile components of the device by demonstrating continued functionality, sterility, and package integrity over the identified shelf life.

(6) Animal simulated-use testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Device must be demonstrated to be effectively inserted, positioned, and removed from the site of use.

(ii) Device must be demonstrated to precipitate surgical smoke particulates to clear the visual field for laparoscopic surgeries.

(iii) Device must be demonstrated to be non-damaging to the site of use and animal subject.

(7) Labeling must identify the following:

(i) Detailed instructions for use.

(ii) Electrical safety and electromagnetic compatibility information.

(iii) A shelf life.

[83 FR 4143, Jan. 30, 2018]

Subpart F—Therapeutic Devices

§ 878.5070 Air-handling apparatus for a surgical operating room.

(a) *Identification.* Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) *Classification.* Class II (special controls). The device, when it is an air handling bench apparatus, an air handling room apparatus, or an air handling enclosure apparatus, 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]

§ 878.5080 Air-handling apparatus accessory.

(a) *Identification.* An air-handling apparatus accessory is a supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.

(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.

[84 FR 14870, Apr. 12, 2019]

§ 878.5350 Needle-type epilator.

(a) *Identification.* A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(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 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 878.5360 Tweezer-type epilator.

(a) *Identification.* The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[63 FR 57060, Oct. 26, 1998]

§ 878.5400 Low level laser system for aesthetic use

(a) *Identification.* A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use.'' See § 878.1(e) for the availability of this guidance document.

[76 FR 20842, Apr. 14, 2011]

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device that is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers such as bedsores.

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

device is FDA's ''Class II Special Controls Guidance: Topical Oxygen Chamber for Extremities.'' See §878.1(e) for the availability of this guidance document.

[76 FR 22807, Apr. 25, 2011]

§ 878.5900 Nonpneumatic tourniquet.

(a) *Identification.* A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.

(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 54 FR 13828, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.5910 Pneumatic tourniquet.

(a) *Identification.* A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.

(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 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A—General Provisions

Sec.

Subpart B [Reserved]

Subpart C—General Hospital and Personal Use Monitoring Devices

Subparts D–E [Reserved]

Subpart F—General Hospital and Personal Use Therapeutic Devices