§ 874.5800 External nasal splint.

(a) *Identification.* An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the 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 § 874.9.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 874.5840 Antistammering device.

(a) *Identification.* An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitative or repetitive speech.

(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 § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.5900 External upper esophageal sphincter compression device.

(a) *Identification.* An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

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

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

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

(i) Mechanical integrity testing (*e.g.*, tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

(i) Appropriate warnings and precautions,

(ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,

(iii) Detailed instructions on how to fit the device to the patient, and

(iv) Instructions for reprocessing of any reusable components.

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

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

(ii) Information on how to correctly wear the device,

(iii) The potential risks and benefits associated with the use of the device,

(iv) Alternative treatments, and

(v) Reprocessing instructions.

[80 FR 46194, Aug. 4, 2015]

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

Subpart A—General Provisions

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876.5861 Pediatric continuous renal replacement therapy system.
876.5862 Hemodialyzer with expanded solute removal profile.
876.5870 Sorbent hemoperfusion system.
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876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.
876.5895 Ostomy irrigator.
876.5900 Ostomy pouch and accessories.
876.5920 Protective garment for incontinence.

876.5930 Rectal control system.
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876.5980 Gastrointestinal tube and accessories.
876.5981 Oral removable palatal space occupying device for weight management and/or weight loss.
876.5982 Ingested, transient, space occupying device for weight management and/or weight loss.
876.5985 Enzyme packed cartridge.
876.5990 Extracorporeal shock wave lithotripter.

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

SOURCE: 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

Subpart A—General Provisions

EDITORIAL NOTE: Nomenclature changes to part 876 appear at 73 FR 35341, June 23, 2008.

§ 876.1 Scope.

(a) This part sets forth the classification of gastroenterology-urology 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 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by §807.87.

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

(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*..

[52 FR 17737, May 11, 1987; 52 FR 22577, June 12, 1987, as amended at 69 FR 77623, Dec. 28, 2004; 78 FR 18233, Mar. 26, 2013]

§ 876.3 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 paragraph (b) 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.

[52 FR 17737, May 11, 1987]

§ 876.9 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 2316, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 876.1050 Endoscopic transhepatic venous access needle.

(a) *Identification.* An endoscopic transhepatic venous access needle is inserted through the liver into the patient's portal/hepatic venous system under endoscopic ultrasound guidance.

It is connected to a separate device intended to measure a physiological parameter.

(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 the patient-contacting components of the device.

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

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

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

(i) Needle crumple testing;

(ii) Tensile testing;

(iii) Dimensional verification for all components; and

(iv) Simulated use testing.

(6) Labeling must include the following:

(i) Instructions for use, including specific instructions regarding device preparation;

(ii) The recommended training for safe use of the device; and

(iii) A shelf life for any sterile components.

[86 FR 71145, Dec. 15, 2021]

§ 876.1075 Gastroenterology-urology biopsy instrument.

(a) *Identification.* A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

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

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.1080 Gastroenterology-urology accessories to a biopsy instrument.

(a) *Identification.* A gastroenterology-urology accessory to a biopsy instrument is an accessory used to remove a specimen of tissue for microscopic examination by cutting or aspiration. This generic type of device includes a syringe for specimen aspiration and a biopsy channel adaptor. This device does not include accessories to biopsy instruments used in other medical specialty areas.

(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 § 876.9.

[84 FR 14869, Apr. 12, 2019]

§ 876.1300 Ingestible telemetric gastrointestinal capsule imaging system.

(a) *Identification.* An ingestible telemetric gastrointestinal capsule imaging system is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance, ''Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging Systems; Final Guidance for Industry and FDA.''

[67 FR 3433, Jan. 24, 2002]

§ 876.1310 Magnetically maneuvered capsule endoscopy system.

(a) *Identification.* A magnetically maneuvered capsule endoscopy system consists of an ingestible capsule and magnetic controller and is used for visualization of the stomach and duodenum. The ingestible capsule contains a camera that wirelessly captures images of the mucosa. The magnetic controller is used outside of the patient and is magnetically coupled with the capsule to control its location and viewing direction.

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

(1) Clinical performance testing with the device under anticipated conditions of use must evaluate visualization of the intended region and document the adverse event profile.

(2) Non-clinical testing data must demonstrate the optical, mechanical, and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested, and detailed protocols must be provided for each test:

(i) A bite test must be performed to ensure that the capsule can withstand extreme cases of biting;

(ii) A pH resistance test must be performed to evaluate integrity of the capsule when exposed to a physiological relevant range of pH values;

(iii) A battery life test must be performed to demonstrate that the capsule's operating time is not constrained by the battery capacity;

(iv) A shelf life test must be performed to demonstrate that the device performs as intended at the proposed shelf life date;

(v) Optical testing must be performed to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, geometric distortion, signal to noise ratio, dynamic range, and image intensity uniformity;

(vi) A color performance test must be performed to compare the color differences between the input scene and output image;

(vii) A photobiological safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided;

(viii) Performance testing must demonstrate that the viewing software clearly presents the current frame rate, which is either adjustable manually by the user or automatically by the device. Testing must demonstrate that the viewing software alerts the user when the video quality is reduced from nominal due to imaging data communication or computation problems;

(ix) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the receiver. This test must include controlled signal attenuation for simulating a non-ideal environment; and

(x) Magnetic field strength testing characterization must be performed to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

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

(4) Electrical safety, thermal safety, mechanical safety, and electromagnetic compatibility testing must be performed.

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

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

(7) Performance data must demonstrate the sterility of any device components labeled sterile.

(8) Human factors testing must demonstrate that the intended users can safely and correctly use the device, based solely on reading the instructions for use.

(9) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device;

(ii) A detailed summary of the clinical testing pertinent to use of the device, including information on effectiveness and device- and procedure-related complications;

(iii) The patient preparation procedure;

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

(v) Magnetic field safe zones;

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

(vii) Reprocessing instructions for reusable components;

(viii) Shelf life for single use components; and

(ix) Use life for reusable components.

(10) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation;

(ii) The patient preparation procedure;

(iii) A brief summary of the clinical study; and

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

[87 FR 26993, May 6, 2022]

§ 876.1330 Colon capsule endoscopy system.

(a) *Identification.* A prescription, single-use ingestible capsule designed to acquire video images during natural propulsion through the digestive system. It is specifically designed to visualize the colon for the detection of polyps. It is intended for use only in patients who had an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.

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

(1) The capsule must be demonstrated to be biocompatible.

(2) Non-clinical testing data must demonstrate the mechanical and functional integrity of the device under physically stressed conditions. The following performance characteristics must be tested and detailed protocols must be provided for each test:

(i) Bite test to ensure that the capsule can withstand extreme cases of biting.

(ii) pH resistance test to evaluate integrity of the capsule when exposed to a range of pH values.

(iii) Battery life test to demonstrate that the capsule's operating time is not constrained by the battery capacity.

(iv) Shelf-life testing to demonstrate that the device performs as intended at the proposed shelf-life date.

(v) Optical testing to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, distortion, signal-to-noise ratio, uniformity, and image artifacts. A test must be performed to evaluate the potential of scratches, caused by travelling through the gastrointestinal tract, on the transparent window of the capsule and their impact on the optical and color performance.

(vi) An optical safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided.

(vii) A color performance test must be provided to compare the color differences between the input scene and output image.

(viii) The video viewer must clearly present the temporal or spatial relationship between any two frames as a real-time lapse or a travel distance. The video viewer must alert the user when the specific video interval is captured at a frame rate lower than the nominal one due to communication errors.

(ix) A performance test evaluating the latency caused by any adaptive algorithm such as adjustable frame rate must be provided.

(x) If the capsule includes a localization module, a localization performance test must be performed to verify the accuracy and precision of locating the capsule position within the colon.

(xi) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the recorder. Controlled signal attenuation should be included for simulating a non-ideal environment.

(xii) Software validation, verification, and hazards analysis must be provided.

(xiii) Electrical equipment safety, including thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed. If the environments of intended use include locations outside of hospitals and clinics, appropriate higher immunity

test levels must be used. Labeling must include appropriate EMC information.

(xiv) Information demonstrating immunity from wireless hazards.

(3) The clinical performance characteristics of the device for the detection of colon polyps must be established. Demonstration of the performance characteristics must include assessment of positive percent agreement and negative percent agreement compared to a clinically acceptable alternative structural imaging method.

(4) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device.

(ii) A detailed summary of the clinical testing pertinent to use of the device, including the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iii) The colon cleansing procedure.

(iv) A detailed summary of the device technical parameters.

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

(vi) An expiration date/shelf life.

(5) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation.

(ii) Patient preparation procedure.

(iii) A brief summary of the clinical study. The summary should not only include the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

[79 FR 28403, May 16, 2014]

§ 876.1400 Stomach pH electrode.

(a) *Identification.* A stomach pH electrode is a device used to measure intragastric and intraesophageal pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996]

§ 876.1450 Esophageal tissue characterization system.

(a) *Identification.* An esophageal tissue characterization system is a device intended for obtaining measurements of electrical properties within esophageal tissue.

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

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

(2) Performance testing must demonstrate the device can accurately measure the designated electrical characteristics.

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

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

(5) Electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety of the device must be performed.

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

(7) Labeling must include:

(i) Specific instructions regarding the proper placement and use of the device;

(ii) Instructions for reprocessing of any reusable components; and

(iii) An expiration date for single use components.

[86 FR 68399, Dec. 2, 2021]

§ 876.1500 Endoscope and accessories.

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into

body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification*—(1) *Class II (special controls).* The device, when it is an endoscope disinfectant basin, which consists solely of a container that holds disinfectant and endoscopes and accessories; an endoscopic magnetic retriever intended for single use; sterile scissors for cystoscope intended for single use; a disposable, non-powered endoscopic grasping/cutting instrument intended for single use; a diagnostic incandescent light source; a fiberoptic photographic light source; a routine fiberoptic light source; an endoscopic sponge carrier; a xenon arc endoscope light source; an endoscope transformer; an LED light source; or a gastroenterology-urology endoscopic guidewire, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807of this chapter, subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001; 83 FR 25914, June 5, 2018; 84 FR 71813, Dec. 30, 2019]

§ 876.1520 Gastrointestinal lesion software detection system.

(a) *Identification.* A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device may contain hardware to support interfacing with an endoscope.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including detection of gastrointestinal lesions and evaluation of all adverse events.

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

(i) Standalone algorithm performance testing;

(ii) Pixel-level comparison of degradation of image quality due to the device;

(iii) Assessment of video delay due to marker annotation; and

(iv) Assessment of real-time endoscopic video delay due to the device.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Performance data must demonstrate electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety testing for any hardware components of the device.

(5) Software verification, validation, and hazard analysis must be provided. Software description must include a detailed, technical description including the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, the associated inputs and outputs, mapping of the software architecture, and a description of the video signal pipeline.

(6) Labeling must include:

(i) Instructions for use, including a detailed description of the device and compatibility information;

(ii) Warnings to avoid overreliance on the device, that the device is not intended to be used for diagnosis or characterization of lesions, and that the device does not replace clinical decision making;

(iii) A summary of the clinical performance testing conducted with the device, including detailed definitions of the study endpoints and statistical confidence intervals; and

(iv) A summary of the standalone performance testing and associated statistical analysis.

[88 FR 10, Jan. 3, 2023]

§ 876.1620 Urodynamics measurement system.

(a) *Identification.* A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydrualic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.1725 Gastrointestinal motility monitoring system.

(a) *Identification.* A gastrointestinal motility monitoring system is a device used to measure peristalic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

(b) *Classification.* Class II (performance standards).

§ 876.1735 Electrogastrography system.

(a) *Identification.* An electrogastrography system (EGG) is a device used to measure gastric myoelectrical activity as an aid in the diagnosis of gastric motility disorders. The device system includes the external recorder, amplifier, skin electrodes, strip chart, cables, analytical software, and other accessories.

(b) *Classification.* Class II (Special Controls). The special controls are as follows:

(1) The sale, distribution and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions:

(i) To describe proper patient set-up prior to the start of the test, including the proper placement of electrodes;

(ii) To describe how background data should be gathered and used to eliminate artifact in the data signal;

(iii) To describe the test protocol (including the measurement of baseline

data) that may be followed to obtain the EGG signal; and

(iv) To explain how data results may be interpreted.

(3) The device design should ensure that the EGG signal is distinguishable from background noise that may interfere with the true gastric myoelectric signal.

(4) Data should be collected to demonstrate that the device has adequate precision and the EGG signal is reproducible and is interpretable.

[64 FR 51444, Sept. 23, 1999]

§ 876.1800 Urine flow or volume measuring system.

(a) *Identification.* A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.

(b) *Classification.* (1) Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 63 FR 59228, Nov. 3, 1998]

Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.

(a) *Identification.* An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.2050 Prostate lesion documentation system.

(a) *Identification.* A prostate lesion documentation system is a prescription device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

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

(1) Non-clinical and clinical performance testing must demonstrate the accuracy and reproducibility of the constructed image.

(2) Appropriate analysis/testing must validate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

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

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

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

(6) The labeling must include specific information needed to ensure proper use of the device.

[80 FR 72900, Nov. 23, 2015]

§ 876.2100 Pressure ulcer management tool.

(a) *Identification.* A pressure ulcer management tool is a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

(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 § 876.9.

[86 FR 70735, Dec. 13, 2021]

Subpart D—Prosthetic Devices

§ 876.3350 Penile inflatable implant.

(a) *Identification.* A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.

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

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (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 July 11, 2000, for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has, on or before July 11, 2000, been found to be substantially equivalent to a penile inflatable implant that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 19658, Apr. 12, 2000]

§ 876.3500 Penile implant surgical accessories.

(a) *Identification.* Penile implant surgical accessories are manual devices designed to be used for surgical procedures associated with the implantation of a penile inflatable implant or penile rigidity implant. This generic type of device includes the cylinder sizer, cylinder insertion tool and needle, device placement tool, connector assembly tool, incision closing tool, corporeal dilator, tubing passer, measurement tool or tape, tubing plug, blunt needle, and hemostat shod tubing.

(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 § 876.9.

[84 FR 14869, Apr. 12, 2019]

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

(b) *Classification.* Class II. The special control for this device is the FDA guidance entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.''

[65 FR 4882, Feb. 2, 2000]

§ 876.3750 Testicular prosthesis.

(a) *Identification.* A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.

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

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 5, 1995, for any testicular prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 5, 1995, been found to be substantially equivalent to a testicular prosthesis that was in commercial distribution before May 28, 1976. Any other testicular prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 60 FR 17216, Apr. 5, 1995]

Subpart E—Surgical Devices

§ 876.4020 Fiberoptic light ureteral catheter.

(a) *Identification.* A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71813, Dec. 30, 2019]

§ 876.4270 Colostomy rod.

(a) *Identification.* A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71813, Dec. 30, 2019]

§ 876.4300 Endoscopic electrosurgical unit and accessories.

(a) *Identification.* An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

(b) *Classification.* Class II (performance standards).

§ 876.4310 Endoscopic electrosurgical clip cutting system.

(a) *Identification.* An endoscopic electrosurgical clip cutting system is a prescription device that applies electrical energy to fragment metallic clips, which are devices placed in the digestive tract to close gastrointestinal perforations, hemorrhages, or perform resection. The system includes instruments that are then used to remove the fragmented clips from the digestive tract.

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

(1) 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) Performance bench testing to evaluate the functionality (including stress, compatibility, usability, and reliability) of the device during use;

(ii) Electrical and thermal safety testing; and

(iii) Electromagnetic compatibility testing.

(2) Animal testing must evaluate tissue damage, including thermal effects, during the clip removal procedure. This testing must also evaluate usability and effectiveness of the device.

(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 intended to be provided sterile.

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

(6) Labeling of the device must include:

(i) Instructions for use, and

(ii) A shelf life for single use components.

[83 FR 27703, June 14, 2018]

§ 876.4330 Endoscopic pancreatic debridement device.

(a) *Identification.* An endoscopic pancreatic debridement device is inserted

via an endoscope and placed through a cystogastrostomy fistula into the pancreatic cavity. It is intended for removal of necrotic tissue from a walled off pancreatic necrosis (WOPN) cavity.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of debridement of walled off pancreatic necrosis and 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) The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

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

(6) 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) Testing of rotational speeds and vacuum pressure;

(ii) Functional testing including testing with all device components and the ability to torque the device; and

(iii) Functional testing in a relevant tissue model to demonstrate the ability to resect and remove tissue.

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

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

(9) Training must be provided so that upon completion of the training program, the user can resect and remove tissue of interest while preserving non-target tissue.

(10) Labeling must include the following:

(i) A summary of the clinical performance testing conducted with the device;

(ii) Instructions for use, including the creation of a conduit for passage of endoscope and device into a walled off pancreatic necrotic cavity;

(iii) Unless clinical performance data demonstrates that it can be removed or modified, a boxed warning stating that the device should not be used in patients with known or suspected pancreatic cancer;

(iv) The recommended training for safe use of the device; and

(v) A shelf life for any sterile components.

[89 FR 72986, Sept. 9, 2024]

§ 876.4340 High intensity ultrasound system for prostate tissue ablation.

(a) *Identification.* A high intensity ultrasound system for prostate tissue ablation is a prescription device that transmits high intensity therapeutic ultrasound energy into the prostate to thermally ablate a defined, targeted volume of tissue, performed under imaging guidance. This classification does not include devices that are intended for the treatment of any specific prostate disease and does not include devices that are intended to ablate non-prostatic tissues/organs.

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

(1) 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) Characterization of acoustic pressure and power output at clinically relevant levels;

(ii) Measurement of targeting accuracy and reproducibility of high intensity ultrasound output;

(iii) Ultrasound-induced heating verification testing at target and non-target tissues;

(iv) Electrical safety testing; and

(v) Electromagnetic compatibility testing.

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

(3) The elements of the device that may contact the patient's mucosal tissue must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that contact the patient's mucosal tissue.

(5) 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.

(6) Performance data must support the instructions for reprocessing all reusable components.

(7) *In vivo* testing must demonstrate that the device thermally ablates targeted tissue in a controlled manner without thermal injury to adjacent, non-target tissues.

(8) Clinical testing must document the adverse event profile, provide evidence of prostatic ablation, and demonstrate that the device performs as intended under anticipated conditions of use.

(9) Training must be provided so that upon completion of the training program, the physician can:

(i) Use all safety features of the device;

(ii) Accurately target the high intensity ultrasound energy within the desired region of the prostate; and

(iii) Perform the ablation procedure in a manner that minimizes damage to non-target tissues.

(10) Labeling must include:

(i) A section that summarizes the clinical testing results, including the adverse event profile and evidence of prostate ablation achieved; and

(ii) An expiration date or shelf life for single use components.

[82 FR 45727, Oct. 2, 2017]

§ 876.4350 Fluid jet system for prostate tissue removal.

(a) *Identification.* A fluid jet system for prostate tissue removal is a prescription device intended for the resection and removal of prostatic tissue for the treatment of benign prostatic hyperplasia. The device cuts tissue by using a pressurized jet of fluid delivered to the prostatic urethra. The device is able to image the treatment area, or pairs with an imaging modality, to monitor treatment progress.

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

(1) Clinical performance testing must evaluate the following:

(i) All adverse events associated with the device, and

(ii) Improvement in lower urinary tract symptoms (LUTS).

(2) Physician training must be provided that includes:

(i) Information on key aspects and use of the device, and

(ii) Information on how to override or stop resection.

(3) Animal testing must demonstrate that the device resects targeted tissue in a controlled manner without injury to adjacent non-target tissues.

(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) Measurement of targeting accuracy and reproducibility of high velocity fluid jet, and

(ii) High pressure fluid jet verification testing at target and non-target tissues.

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

(6) The patient-contacting elements of the device must be demonstrated to be biocompatible.

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

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

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

(10) Performance data must validate the instructions for reprocessing and reliability of reusable components.

(11) Labeling must include the following:

(i) A section that summarizes the clinical testing results, including the adverse event profile and improvement in LUTS;

(ii) A shelf life for single use components;

(iii) A use life for reusable components; and

(iv) Reprocessing instructions for reusable components.

[83 FR 27897, June 15, 2018]

§ 876.4370 Gastroenterology-urology evacuator.

(a) *Identification.* A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump.

(b) *Classification.* (1) Class II (special controls) for the gastroenterology-urology evacuator when other than manually powered. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

(2) Class I for the gastroenterology-urology evacuator when manually powered. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 63 FR 59228, Nov. 3, 1998]

§ 876.4400 Hemorrhoidal ligator.

(a) *Identification.* A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.

(b) *Classification.* Class II (special controls). Except for a hemostatic metal clip intended for use in the gastrointestinal tract, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71813, Dec. 30, 2019]

§ 876.4480 Electrohydraulic lithotriptor.

(a) *Identification.* An electrohydraulic lithotriptor is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.

(b) *Classification.* Class II. The special control for this device is FDA's ''Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters.''

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 17145, Mar. 31, 2000]

§ 876.4500 Mechanical lithotriptor.

(a) *Identification.* A mechanical lithotriptor is a device with steel jaws that is inserted into the urinary bladder through the urethra to grasp and crush bladder stones.

(b) *Classification.* Class II (special controls). The device, when it is a biliary mechanical lithotripter, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71813, Dec. 30, 2019]

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

(a) *Identification.* A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.4560 Ribdam.

(a) *Identification.* A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.4590 Interlocking urethral sound.

(a) *Identification.* An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.4620 Ureteral stent.

(a) *Identification.* A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

(b) *Classification.* Class II (performance standards).

§ 876.4630 Ureteral stent accessories.

(a) *Identification.* Ureteral stent accessories aid in the insertion of the ureteral stent that is placed into the ureter to provide ureteral rigidity and allow the passage of urine. This generic type of device includes the stent positioner, wire guide, and pigtail straightener.

(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 § 876.9.

[84 FR 14870, Apr. 12, 2019]

§ 876.4650 Water jet renal stone dislodger system.

(a) *Identification.* A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.4680 Ureteral stone dislodger.

(a) *Identification.* A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification.* A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining

retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop. A manual surgical instrument that is intended specifically for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures are classified under § 884.4910 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25049, June 12, 1989; 66 FR 38801, July 25, 2001; 82 FR 12171, Mar. 1, 2017]

§ 876.4770 Urethrotome.

(a) *Identification.* A urethrotome is a device that is inserted into the urethra and used to cut urethral strictures and enlarge the urethra. It is a metal instrument equipped with a dorsal-fin cutting blade which can be elevated from its sheath. Some urethrotomes incorporate an optical channel for visual control.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71813, Dec. 30, 2019]

§ 876.4890 Urological table and accessories.

(a) *Identification.* A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually or electrically.

(b) *Classification.* (1) Class II (special controls) for the electrically powered urological table and accessories. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 63 FR 59228, Nov. 3, 1998; 66 FR 38801, July 25, 2001]

Subpart F—Therapeutic Devices

§ 876.5010 Biliary catheter and accessories.

(a) *Identification.* A biliary catheter and accessories is a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap.

(b) *Classification.* Class II (special controls). The device, when it is a bile collecting bag or a surgical biliary catheter that does not include a balloon component, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5011 Metallic biliary stent system for benign strictures.

(a) *Identification.* A metallic biliary stent system for benign strictures is a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the biliary stent in the bile duct. This device type is not intended for use in the vasculature.

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

(1) Clinical performance testing must demonstrate or provide the following:

(i) The ability to safely place and subsequently remove the stent after the maximum labeled indwell period.

(ii) All adverse event data including bile duct obstruction and trauma to the bile duct.

(iii) The stent resolves strictures during the maximum labeled indwell period.

(iv) Stricture resolution is maintained post-stent removal.

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

(i) Corrosion testing to demonstrate that the stent maintains its integrity during indwell and does not release potentially toxic levels of leachables.

(ii) Stent dimensional testing supports the intended use.

(iii) Compression and expansion forces must be characterized.

(iv) The delivery catheter must deliver the stent to the intended location and the stent must not be adversely impacted by the delivery catheter during deployment and catheter withdrawal.

(v) The delivery system must withstand clinically anticipated forces.

(vi) Compatibility in a magnetic resonance environment.

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

(4) Performance data must demonstrate the sterility of the device components intended to be provided sterile.

(5) Shelf life testing must demonstrate that the device maintains its performance characteristics and that packaging maintains sterility for the duration of the labeled shelf life.

(6) Labeling for the device must include:

(i) A detailed summary of the clinical testing including device effectiveness, and device- and procedure-related adverse events.

(ii) Appropriate warning(s) to accurately ensure usage of the device for the intended patient population.

(iii) Shelf life.

(iv) Compatibility information for use in the magnetic resonance environment.

(v) Stent foreshortening information supported by dimensional testing.

[81 FR 45231, July 13, 2016]

§ 876.5012 Biliary stent, drain, and dilator accessories.

(a) *Identification.* Biliary stent, drain, and dilator accessories are manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.

(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 § 876.9.

[84 FR 14870, Apr. 12, 2019]

§ 876.5015 Pancreatic drainage stent and delivery system.

(a) *Identification.* A pancreatic drainage stent is a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

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

(1) The device and elements of the delivery device that may contact the patient 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 testing data must demonstrate that the stent and delivery system perform as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing of the stent and delivery system must be conducted under simulated use conditions.

(ii) Removal force testing must be conducted. The removal force testing must demonstrate that the stent can be safely removed, and that the stent

will remain in place when subjected to forces encountered during use.

(iii) Expansion force testing must be conducted. The expansion force must demonstrate that the forces exerted by the stent will not damage the tissue surrounding the stent.

(iv) Compression force testing must be conducted. The compression force must demonstrate that the stent will withstand the forces encountered during use.

(v) Dimensional verification testing must be conducted.

(vi) Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

(vii) Fatigue testing must be conducted. Material strength must demonstrate that the stent will withstand forces encountered during use.

(viii) Corrosion testing must be conducted. Corrosion resistance must demonstrate that the stent will withstand conditions encountered during use.

(5) Non-clinical testing must evaluate the compatibility of the stent in a magnetic resonance (MR) environment.

(6) Well-documented clinical experience must demonstrate safe and effective use, and capture any adverse events observed during clinical use.

(7) Labeling must include the following:

(i) Appropriate instructions, warnings, cautions, limitations, and information related to the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(ii) A warning that the safety and patency of the stent has not been established beyond the duration of the documented clinical experience.

(iii) Specific instructions and the qualifications and clinical training needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(iv) Information on the patient population for which the device has been demonstrated to be effective.

(v) A detailed summary of the clinical experience pertinent to use of the device.

(vi) A detailed summary of the device technical parameters.

(vii) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(viii) An expiration date/shelf life.

[79 FR 30724, May 29, 2014]

§ 876.5020 External penile rigidity devices.

(a) *Identification.* External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints which are mechanical, powered, or pneumatic devices.

(b) *Classification.* Class II (special controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special control for these devices is the FDA guidance document entitled ''Class II Special Controls Guidance Document: External Penile Rigidity Devices.'' See § 876.1(e) for the availability of this guidance document.

[69 FR 77623, Dec. 28, 2004]

§ 876.5025 Vibrator for climax control of premature ejaculation.

(a) *Identification.* A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special controls for this device are:

(1) The labeling must include specific instructions regarding the proper placement and use of the device.

(2) The portions of the device that contact the patient must be demonstrated to be biocompatible.

(3) Appropriate analysis/testing must demonstrate electromagnetic compatibility safety, electrical safety, and thermal safety of the device.

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

[80 FR 30355, May 28, 2015, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5026 Non-implanted electrical stimulation device for management of premature ejaculation.

(a) *Identification.* A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

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

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

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

(3) 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) Mechanical performance;

(ii) Electrical stimulation parameters; and

(iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

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

(6) Labeling must include:

(i) Specific instructions regarding safe placement and correct use of the device;

(ii) Warning(s) against use by patients with active implanted medical devices; and

(iii) A shelf life.

[87 FR 34166, Apr. 5, 2022]

§ 876.5030 Continent ileostomy catheter.

(a) *Identification.* A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38801, July 25, 2001]

§ 876.5090 Suprapubic urological catheter and accessories.

(a) *Identification.* A suprapubic urological catheter and accessories is a flexible tubular device that is inserted through the abdominal wall into the urinary bladder with the aid of a trocar and cannula. The device is used to pass fluids to and from the urinary tract. This generic type of device includes the suprapubic catheter and tube, Malecot catheter, catheter punch instrument, suprapubic drainage tube, and the suprapubic cannula and trocar.

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

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.5100 Suprapubic catheter accessories.

(a) *Identification.* Suprapubic catheter accessories are manual devices that are used to facilitate the placement of a suprapubic catheter. This generic type of device includes the introducer, access dilator, and peel-away sheath.

(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 § 876.9.

[84 FR 14870, Apr. 12, 2019]

§ 876.5130 Urological catheter and accessories.

(a) *Identification.* A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudé catheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-urological irrigation tray (for urological use).

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

(2) Class I for the ureteral stylet (guidewire), stylet for gastrourological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.5140 Urethral insert with pump for bladder drainage.

(a) *Identification.* A urethral insert with pump for bladder drainage is a catheter-like device with internal pump mechanism that is placed in the urethra. Under patient control the internal pump draws urine out of the bladder when voiding is desired, and blocks urine flow when continence is desired. The device is intended for use by women who cannot empty their bladder due to impaired detrusor contractility.

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

(1) The elements of the device that may contact the urinary tract must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of the device components that contact the urinary tract.

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

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

(i) Urine flow rate testing.

(ii) Valve integrity testing.

(iii) Bladder neck retention force testing.

(iv) Pump/valve endurance testing.

(v) Encrustation testing.

(vi) Remote control reliability, mechanical integrity, and battery life testing.

(5) Clinical testing must demonstrate safe and effective use, document the device acceptance rate and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(6) Labeling must include:

(i) Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) Statement of the maximum insert indwelling period.

(iii) Information on the patient education and support program prior to and during initial device use.

(iv) Information on the patient population for which the device has been demonstrated to be safe and effective.

(v) Information on how the device operates and the recommended treatment regimen.

(vi) A detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.

(vii) An expiration date/shelf life.

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

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

(ii) Information on how the device operates and the recommended treatment regimen.

(iii) Information on the patient education and support program prior to and during initial device use.

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

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

(vi) Post-insertion care instructions.

(vii) Alternative treatments.

[80 FR 18309, Apr. 6, 2015]

§ 876.5160 Urological clamp.

(a) *Identification.* A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

(b) *Classification.* Class I (general controls). Except when intended for internal use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1963, as amended at 65 FR 2317, Jan. 14, 2000; 84 FR 71814, Dec. 30, 2019]

§ 876.5210 Enema kit.

(a) *Identification.* An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (§ 876.5220).

(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 § 876.9. 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 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[48 FR 53023, Nov. 23, 1963, as amended at 65 FR 2317, Jan. 14, 2000]

§ 876.5220 Colonic irrigation system.

(a) *Identification.* A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (§ 876.5210).

(b) *Classification.* (1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

(2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

(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 December 26, 1996 for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]

§ 876.5250 Urine collector and accessories.

(a) *Identification.* A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are:

(1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and

(2) A urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

(b) *Classification*—(1) *Class II (special controls) for a urine collector and accessories intended to be connected to an indwelling catheter.* The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

(2) *Class I (general controls).* For a urine collector and accessories not intended to be connected to an indwelling catheter, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. 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, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998; 65 FR 2317, Jan. 14, 2000; 66 FR 38802, July 25, 2001; 73 FR 34860, June 19, 2008]

§ 876.5270 Implanted electrical urinary continence device.

(a) *Identification.* An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

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

(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 December 26, 1996 for any implanted electrical urinary continence device that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted electrical urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted electrical urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

(a) *Identification.* An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra. The totally implanted device may consist of a static pressure pad, or a system with a container of radiopaque fluid in the abdomen and a manual pump and valve under the skin surface that is connected by tubing to an adjustable pressure pad or to a cuff around the urethra. The fluid is pumped as needed from the container to inflate the pad or cuff to pass on the urethra.

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

(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 December 26, 2000, for any implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May

28, 1976, or that has, on or before December 26, 2000, been found to be substantially equivalent to an implanted mechanical/hydraulic urinary continence device that was in commercial distribution before May 28, 1976. Any other implanted mechanical/hydraulic urinary continence device shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 57731, Sept. 26, 2000]

§ 876.5290 Implanted mechanical/hydraulic urinary continence device surgical accessories.

(a) *Identification.* Implanted mechanical/hydraulic urinary continence device surgical accessories are manual devices designed to be used for surgical procedures associated with the implantation of an implanted mechanical/hydraulic urinary continence device. This generic type of device includes the measurement tool or tape, connector assembly tool, tubing plug, incision closing tool, tubing passer, blunt needle, and hemostat shod tubing.

(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 § 876.9.

[84 FR 14870, Apr. 12, 2019]

§ 876.5310 Nonimplanted, peripheral electrical continence device.

(a) *Identification.* A nonimplanted, peripheral electrical continence device is a device that consists of an electrode that is connected by an electrical cable to a battery-powered pulse source. The electrode is placed onto or inserted into the body at a peripheral location and used to stimulate the nerves associated with pelvic floor function to maintain urinary continence. When necessary, the electrode may be removed by the user.

(b) *Classification.* Class II, subject to the following special controls:

(1) That sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) That the labeling must bear all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including a detailed summary of the clinical information upon which the instructions are based.

[65 FR 18237, Apr. 7, 2000]

§ 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§ 884.5940).

(b) *Classification.* Class II (performance standards).

§ 876.5330 Transcutaneous electrical continence device.

(a) *Identification.* A transcutaneous electrical continence device consists of cutaneous electrodes that are used to apply external stimulation to reduce urinary incontinence.

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

(1) Non-clinical performance testing must characterize the electrical stimulation, including the following: Waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

(2) The patient-contacting materials must be demonstrated to be biocompatible.

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

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

(5) Labeling must include the following:

(i) Instructions for use, including specific instructions regarding the proper placement of electrodes;

(ii) A summary of electrical stimulation parameters; and

(iii) Cleaning instructions and reuse information.

[86 FR 73971, Dec. 29, 2021]

§ 876.5340 Nonimplanted nerve stimulator for functional abdominal pain relief.

(a) *Identification.* A nonimplanted nerve stimulator for functional abdominal pain relief is a device that stimulates nerves remotely from the source of pain with the intent to relieve functional abdominal pain. This generic type of device does not include devices designed to relieve pelvic pain.

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

(3) Electrical performance testing of the device and electrodes must be conducted to validate the specified electrical output and duration of stimulation of the device.

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

(5) Sterility testing of the percutaneous components of the device must be performed.

(6) Shelf life testing must be performed to demonstrate continued sterility, package integrity, and device functionality over the labeled shelf life.

(7) Labeling must include the following:

(i) A detailed summary of the device technical parameters;

(ii) A warning stating that the device is only for use on clean, intact skin;

(iii) Instructions for use, including placement of the device on the patient; and

(iv) A shelf life.

[86 FR 71143, Dec. 15, 2021]

§ 876.5365 Esophageal dilator.

(a) *Identification.* An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5450 Rectal dilator.

(a) *Identification.* A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38802, July 25, 2001]

§ 876.5470 Ureteral dilator.

(a) *Identification.* A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.

(b) *Classification.* Class II (performance standards).

§ 876.5520 Urethral dilator.

(a) *Identification.* A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the

mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower.

(b) *Classification.* (1) Class II (special controls). Except when it is a mechanical urethral dilator, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38802, July 25, 2001; 84 FR 71814, Dec. 30, 2019]

§ 876.5530 Implantable transprostatic tissue retractor system.

(a) *Identification.* An implantable transprostatic tissue retractor system is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future prostate procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia in men.

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

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

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

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

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

(i) Deployment testing must be conducted.

(ii) Mechanical strength must be conducted.

(iii) Resistance-to-degradation testing must be conducted.

(5) Non-clinical testing must evaluate the compatibility of the device in a magnetic resonance environment.

(6) In vivo testing must demonstrate safe and effective use, assess the impact of the implants on the ability to perform subsequent treatments, document the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing must be conducted.

(ii) Implant migration must be conducted.

(7) Labeling must bear all information required for safe and effective use of the device, and must include:

(i) Specific instructions, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) Information on the patient population for which the device has been demonstrated to be effective.

(iii) A detailed summary of the device technical parameters.

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

(v) An expiration date/shelf life.

(vi) A detailed summary of the device- and procedure-related complications or adverse events pertinent to use of the device.

[79 FR 43249, July 25, 2014]

§ 876.5540 Blood access device and accessories.

(a) *Identification.* A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for

hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.

(1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various catheters, shunts, and connectors specifically designed to provide access to blood. Examples include single and double lumen catheters with cuff(s), fully subcutaneous port-catheter systems, and A–V shunt cannulae (with vessel tips). The implanted blood access device may also contain coatings or additives which may provide additional functionality to the device.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).

(3) Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).

(b) *Classification.* (1) Class II (special controls) for the implanted blood access device. The special controls for this device are:

(i) Components of the device that come into human contact must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.

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

(A) Pressure versus flow rates for both arterial and venous lumens, from the minimum flow rate to the maximum flow rate in 100 milliliter per minute increments, must be established. The fluid and its viscosity used during testing must be stated.

(B) Recirculation rates for both forward and reverse flow configurations must be established, along with the protocol used to perform the assay, which must be provided.

(C) Priming volumes must be established.

(D) Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

(E) Air leakage testing and liquid leakage testing must be conducted.

(F) Testing of the repeated clamping of the extensions of the catheter that simulates use over the life of the device must be conducted, and retested for leakage.

(G) Mechanical hemolysis testing must be conducted for new or altered device designs that affect the blood flow pattern.

(H) Chemical tolerance of the device to repeated exposure to commonly used disinfection agents must be established.

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

(iv) Performance data must support the shelf life of the device for continued sterility, package integrity, and functionality over the requested shelf life that must include tensile, repeated clamping, and leakage testing.

(v) Labeling of implanted blood access devices for hemodialysis must include the following:

(A) Labeling must provide arterial and venous pressure versus flow rates, either in tabular or graphical format. The fluid and its viscosity used during testing must be stated.

(B) Labeling must specify the forward and reverse recirculation rates.

(C) Labeling must provide the arterial and venous priming volumes.

(D) Labeling must specify an expiration date.

(E) Labeling must identify any disinfecting agents that cannot be used to clean any components of the device.

(F) Any contraindicated disinfecting agents due to material incompatibility must be identified by printing a warning on the catheter. Alternatively, contraindicated disinfecting agents must be identified by a label affixed to the patient's medical record and with written instructions provided directly to the patient.

(G) Labeling must include a patient implant card.

(H) The labeling must contain comprehensive instructions for the following:

(*1*) Preparation and insertion of the device, including recommended site of insertion, method of insertion, and a reference on the proper location for tip placement;

(*2*) Proper care and maintenance of the device and device exit site;

(*3*) Removal of the device;

(*4*) Anticoagulation;

(*5*) Management of obstruction and thrombus formation; and

(*6*) Qualifications for clinical providers performing the insertion, maintenance, and removal of the devices.

(vi) In addition to Special Controls in paragraphs (b)(1)(i) through (v) of this section, implanted blood access devices that include subcutaneous ports must include the following:

(A) Labeling must include the recommended type of needle for access as well as detailed instructions for care and maintenance of the port, subcutaneous pocket, and skin overlying the port.

(B) Performance testing must include results on repeated use of the ports that simulates use over the intended life of the device.

(C) Clinical performance testing must demonstrate safe and effective use and capture any adverse events observed during clinical use.

(vii) In addition to Special Controls in paragraphs (b)(1)(i) through (v) of this section, implanted blood access devices with coatings or additives must include the following:

(A) A description and material characterization of the coating or additive material, the purpose of the coating or additive, duration of effectiveness, and how and where the coating is applied.

(B) An identification in the labeling of any coatings or additives and a summary of the results of performance testing for any coating or material with special characteristics, such as decreased thrombus formation or antimicrobial properties.

(C) A Warning Statement in the labeling for potential allergic reactions including anaphylaxis if the coating or additive contains known allergens.

(D) Performance data must demonstrate efficacy of the coating or additive and the duration of effectiveness.

(viii) The following must be included for A–V shunt cannulae (with vessel tips):

(A) The device must comply with Special Controls in paragraphs (b)(1)(i) through (v) of this section with the exception of paragraphs (b)(1)(ii)(B), (b)(1)(ii)(C), (b)(1)(v)(B), and (b)(1)(v)(C), which do not apply.

(B) Labeling must include Warning Statements to address the potential for vascular access steal syndrome, arterial stenosis, arterial thrombosis, and hemorrhage including exsanguination given that the device accesses the arterial circulation.

(C) Clinical performance testing must demonstrate safe and effective use and capture any adverse events observed during clinical use.

(2) Class II (performance standards) for the nonimplanted blood access device.

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 1122, Jan. 16, 1996; 66 FR 38802, July 25, 2001; 79 FR 43245, July 25, 2014]

§ 876.5550 Prostatic artery embolization device.

(a) *Identification.* A prostatic artery embolization device is an intravascular implant intended to occlude the prostatic arteries to prevent blood flow to the targeted area of the prostate, resulting in a reduction of lower urinary tract symptoms related to benign prostatic hyperplasia. This does not include cyanoacrylates and other embolic agents which act by in situ polymerization or precipitation, or embolization devices used in neurovascular applications (see 21 CFR 882.5950).

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

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

(2) 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) Evaluation of suitability for injection through catheters intended for use in embolization; and

(ii) Evaluation of the size distribution of the device.

(3) Performance data must support the sterility and pyrogenicity 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 identified shelf life.

(5) Clinical data must evaluate post-embolization damage due to non-target embolization under anticipated use conditions.

(6) The labeling must include:

(i) Specific instructions on safe device preparation and use;

(ii) The device shelf life;

(iii) Data regarding urinary retention; and

(iv) Data regarding post-prostatic artery embolization syndrome.

[82 FR 52651, Nov. 14, 2017]

§ 876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.

(a) *Identification.* A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (§ 876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials.

(b) *Classification.* Class II (performance standards).

§ 876.5630 Peritoneal dialysis system and accessories.

(a) *Identification.* (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system.

(2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritioneal catheter, intended to remain in the peritoneal cavity for less

than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.

(3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.

(4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or ''cycler systems'') or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or ''reverse osmosis'' systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.

(b) *Classification.* Class II (special controls). The following accessories are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §876.9: A catheter finger grip that is non-patient contacting and intended for single use with a peritoneal catheter; a continuous ambulatory peritoneal dialysis (CAPD) belt; and a catheter stand that does not include weigh scales.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5665 Water purification system for hemodialysis.

(a) *Identification.* A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

(b) *Classification.* Class II (special controls). The device, when it is a water purification subsystem disinfectant, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5820 Hemodialysis system and accessories.

(a) *Identification.* A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§876.5540) to the blood compartment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§876.5830) or dialyzers of high permeability (§876.5860).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the

dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860).

(4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

(b) *Classification.* (1) Class II (performance standards) for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.

(2) Class I for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties. 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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

§ 876.5830 Hemodialyzer with disposable insert (Kiil type).

(a) *Identification.* A hemodialyzer with disposable inserts (Kiil type) is a device that is used as a part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that includes disposable inserts consisting of layers of semipermeable membranes which are sandwiched between support plates. The device is used with the extracorporeal blood system and the dialysate delivery system of the hemodialysis system and accessories (§ 876.5820).

(b) *Classification.* Class II (performance standards).

[48 FR 53023, Nov. 23, 1983, as amended at 53 FR 11253, Apr. 6, 1988]

§ 876.5860 High permeability hemodialysis system.

(a) *Identification.* A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system (§ 876.5820), the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (K_{uf}) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or anther method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery

system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

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

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Device—Part I: Evaluation and Testing,' ''

(2) ''Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers,''

(3) ''Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems,''

(4) ''Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis,'' and

(5) ''Guidance for Hemodialyzer Reuse Labeling.''

[65 FR 17145, Mar. 31, 2000]

§ 876.5861 Pediatric continuous renal replacement therapy system.

(a) *Identification*. A pediatric continuous renal replacement therapy hemodialysis system is a device intended for use as an artificial kidney system for the management of pediatric patients with acute kidney injury and/or fluid overload by performing such therapies as hemodialysis, hemofiltration, hemodiafiltration, and isolated ultrafiltration. Using a hemodialyzer with a semipermeable membrane, the hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via ultrafiltration) and/or diffusion (via a concentration gradient in dialysate). The hemodialysis delivery machine, with an automated ultrafiltration controller, controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. During treatment, a patient's blood is circulated through the blood tubing set connected to the hemodialyzer's blood compartment. Blood access devices and accessories for hemodialysis required for the prescribed treatment are regulated under § 876.5540.

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

(1) Clinical performance testing must confirm the safety and the accuracy, precision, and reproducibility of the non-clinical performance data under anticipated conditions of use.

(2) Usability testing must demonstrate that a user can correctly use the hemodialysis delivery device based solely on reading the instructions for use.

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

(i) Hemodialysis delivery system performance testing must include:

(A) Fluid flow accuracy testing; and

(B) Functional testing of system components including sensors, pumps, and scales to acceptance criteria.

(ii) Hemodialyzer performance testing must include:

(A) Ultrafiltration;

(B) Blood and dialysate pressure drop;

(C) Clearance rates;

(D) Sieving coefficients;

(E) Mechanical hemolysis;

(F) Structural integrity;

(G) Blood compartment integrity;

(H) Volume of the blood compartment; and

(I) Chemical analysis of the dialyzer membrane.

(iii) Blood tubing set performance testing must include:

(A) Pressure leak testing;

(B) Worst-case endurance testing;

(C) Priming volume assessment;

(D) Tensile testing of joints and materials of all tubing segments;

(E) Pressure transducer leak testing;

(F) Clamp occlusion;

(G) Mechanical hemolysis; and

(H) Kink testing.

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

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

(6) The tissue-contacting components of the device must be demonstrated to be biocompatible.

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

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

(9) The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

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

(11) Device labeling must include:

(i) Hemodialysis delivery system labeling must provide detailed information regarding the safe use of the dialysis machine, including:

(A) Overall description of the device and individual components or accessories labeled for use with the delivery system;

(B) Description of the safety-related components included in the system;

(C) Identification of operational parameters;

(D) Alarms and troubleshooting information;

(E) Cleaning, disinfection, and preventative maintenance procedures; and

(F) A statement that the device is intended for use by operators trained in the administration of continuous renal replacement therapy and in the management of its complications.

(ii) Hemodialyzer labeling must include:

(A) Description of compatibility;

(B) Shelf life;

(C) Storage conditions;

(D) Instructions for the preparation of the hemodialyzer, initiation of dialysis, troubleshooting, and discontinuance of dialysis;

(E) Membrane surface area, priming (blood) volume, maximum transmembrane pressure, maximum blood flow and maximum dialysate rate for each model;

(F) Summary of the in vitro performance data; and

(G) A non-pyrogenic statement.

(iii) Blood tubing set labeling must provide detailed information regarding the safe use of the device, including:

(A) Description of compatibility;

(B) Shelf life;

(C) Storage conditions;

(D) Identification of the components in the package;

(E) Total length of the arterial and venous tubing sets;

(F) Outer diameter (OD) of the pump segment;

(G) Priming volume;

(H) Identification of the hemodialysis delivery systems which are compatible with the blood tubing set;

(I) Identification of the largest gauge needle that can be used with the injection port, if applicable; and

(J) Identification of the maximum operating pressures for the transducer protectors.

[89 FR 75496, Sept. 16, 2024]

§ 876.5862 Hemodialyzer with expanded solute removal profile.

(a) *Identification.* A hemodialyzer with expanded solute removal profile is a device intended for use a part of an artificial kidney system for the treatment of patients with renal failure by performing such therapies as hemodialysis, hemofiltration, and hemodiafiltration. A hemodialyzer with expanded solute removal profile includes modifications to the semipermeable membrane that allows for increased removal of uremic retention solutes compared with standard high-flux hemodialyzers of the high permeability hemodialysis system classification (§ 876.5860), including solutes at the upper end of the ''middle'' molecular weight range (0.5 kDa to 60 kDa). This device is intended to be used with the extracorporeal hemodialysis delivery systems, blood tubing sets, blood access devices, and accessories regulated under §§ 876.5820, 876.5860, 876.5540, and/or 876.5600.

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

(1) Clinical performance testing under anticipated conditions of use must evaluate the solute removal profile and document all adverse events.

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

(i) Ultrafiltration;

(ii) Blood and dialysate pressure drop;

(iii) Clearance rates;

(iv) Sieving coefficients;

(v) Mechanical hemolysis;

(vi) Structural integrity;

(vii) Blood compartment integrity;

(viii) Volume of the blood compartment; and

(ix) Endotoxin retention of the dialyzer membrane.

(3) The tissue-contacting components of the device must be demonstrated to be biocompatible. Biocompatibility evaluation must include a chemical analysis of the dialyzer membrane.

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

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

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

(7) Device labeling must include:

(i) Shelf life;

(ii) Storage conditions;

(iii) Instructions for the preparation of the hemodialyzer, initiation of dialysis, troubleshooting, and discontinuance of dialysis;

(iv) Membrane surface area, priming (blood) volume, maximum transmembrane pressure, maximum blood flow and maximum dialysate rate for each model;

(v) A non-pyrogenic statement;

(vi) A summary of the in vitro performance data, provided in tabular form; and

(vii) A summary of the clinical performance data.

[89 FR 72716, Sept. 6, 2024]

§ 876.5870 Sorbent hemoperfusion system.

(a) *Identification.* A sorbent hemoperfusion system is a prescription device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (§ 876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.

(b) *Classification.* (1) Class II (special controls) when the device is intended for the treatment of poisoning and drug overdose. The special controls for this device are:

(i) The device must be demonstrated to be biocompatible;

(ii) Performance data must demonstrate the mechanical integrity of the device (e.g., tensile, flexural, and structural strength), including testing for the possibility of leaks, ruptures, release of particles, and/or disconnections under anticipated conditions of use;

(iii) Performance data must demonstrate device sterility and shelf life;

(iv) Bench performance testing must demonstrate device functionality in terms of substances, toxins, and drugs removed by the device, and the extent that these are removed when the device is used according to its labeling, and to validate the device's safeguards;

(v) A summary of clinical experience with the device that discusses and analyzes device safety and performance, including a list of adverse events observed during the testing, must be provided;

(vi) Labeling must include the following:

(A) A detailed summary of the device-related and procedure-related complications pertinent to the use of the device;

(B) A summary of the performance data provided for the device, including a list of the drugs and/or poisons the device has been demonstrated to remove, and the extent for removal/depletion; and

(vii) For those devices that incorporate electrical components, appropriate analysis and testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(2) Class III (premarket approval) when the device is intended for the treatment of hepatic coma and metabolic disturbances.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA by April 17, 2014, for any sorbent hemoperfusion system indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976, or that has, by April 17, 2014, been found to be substantially equivalent to any sorbent hemoperfusion device indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976. Any other sorbent hemoperfusion system device indicated for treatment of hepatic coma or metabolic disturbances shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[79 FR 3094, Jan. 17, 2014]

§ 876.5880 Isolated kidney perfusion and transport system and accessories.

(a) *Identification.* An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

(b) *Classification.* Class II (performance standards).

§ 876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.

(a) *Identification.* Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.

(b) *Classification.* Class II (special controls): FDA guidance document, ''Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Processing Applications; Final Guidance for Industry and FDA Reviewers.''

[66 FR 27025, May 16, 2001]

§ 876.5895 Ostomy irrigator.

(a) *Identification.* An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 84 FR 71814, Dec. 30, 2019]

§ 876.5900 Ostomy pouch and accessories.

(a) *Identification.* An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type

of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

(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 § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

§ 876.5920 Protective garment for incontinence.

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(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 § 876.9. The device is also 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, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

§ 876.5930 Rectal control system.

(a) *Identification.* A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

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

(1) Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.

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

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

(5) Non-clinical (bench) testing must demonstrate that the device does not:

(i) Enhance the growth of *Staphylococcus aureus.*

(ii) Increase production of Toxic Shock Syndrome Toxin-1 by *S. aureus.*

(iii) Alter the growth of normal vaginal flora.

(6) Labeling must include:

(i) Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.

(ii) The intended patient population and the intended use environment.

(iii) Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.

(iv) A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.

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

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

(ii) Information on how the device operates and the recommended device maintenance (*i.e.*, care instructions), including cleaning and disinfection.

(iii) Information on the patient population for which there was a favorable benefit/risk assessment.

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

[80 FR 30933, June 1, 2015]

§ 876.5955 Peritoneo-venous shunt.

(a) *Identification.* A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure activated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

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

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(2) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),'' and

(3) Backflow specification and testing to prevent reflux of blood into the shunt.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 17145, Mar. 31, 2000]

§ 876.5960 Computerized behavioral therapy device for treating symptoms of gastrointestinal conditions.

(a) *Identification.* A computerized behavioral therapy device for treating symptoms of gastrointestinal conditions is a prescription device intended to provide a computerized version of condition-specific therapy as an adjunct to standard of care treatments to patients with gastrointestinal conditions.

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

(1) Clinical data must be provided to fulfill the following:

(i) Describe a model of therapy for the indicated gastrointestinal conditions;

(ii) Validate the model of therapy as implemented by the device using a clinically defined endpoint; and

(iii) Evaluate all adverse events.

(2) Software must be described in detail in the software requirements specification and software design specification. Software verification, validation, and hazard analysis must be performed. Software documentation must demonstrate that the device effectively implements the behavioral therapy model.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Labeling:

(i) Labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the device is not intended for use in lieu of a standard therapeutic intervention or to represent a substitution for the patient's medication;

(iv) Patient and physician labeling must include a warning to seek medical care if a patient has feelings or thoughts of harming themselves or others; and

(v) Physician and patient labeling must include a summary of the clinical testing with the device.

[88 FR 3636, Jan. 20, 2023]

§ 876.5970 Hernia support.

(a) *Identification.* A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

(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 § 876.9. The device is also 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, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[48 FR 53023, Nov. 23, 1983, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

§ 876.5980 Gastrointestinal tube and accessories.

(a) *Identification.* A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).

(b) *Classification.* (1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory or a gastronomy tube holder accessory is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

(2) Class I (general controls) for the dissolvable nasogastric feed tube guide for the nasogastric tube. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[49 FR 573, Jan. 5, 1984, as amended at 65 FR 2317, Jan. 14, 2000; 65 FR 76932, Dec. 8, 2000; 84 FR 71814, Dec. 30, 2019]

§ 876.5981 Oral removable palatal space occupying device for weight management and/or weight loss.

(a) *Identification.* An oral removable palatal space occupying device for weight management and/or weight loss is a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions

(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 for its intended use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

(i) Mechanical testing must demonstrate that the device performs as intended for the labeled use life and does not create forces that result in movement of teeth and damage to teeth.

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

(iii) Software verification and validation must demonstrate that the device performs as intended.

(iv) Battery testing must demonstrate that the device battery performs as intended.

(3) Clinical performance testing must demonstrate the device performs as intended and must include an evaluation for choking.

(4) Device labeling must address the following:

(i) Patient labeling must state:

(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(ii) Physician labeling must state:

(A) The clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

(B) Treatment must be offered in combination with a behavioral modification program;

(C) Instructions on how to use the device as intended; and

(D) The use life of the device.

(5) Training must be provided to health professionals that includes procedures for determining a patient's oral health status, instructions for

making the palatal mold, and assessment of issues with the device that may require service by the manufacturer.

[82 FR 35069, July 28, 2017]

§ 876.5982 Ingested, transient, space occupying device for weight management and/or weight loss.

(a) *Identification.* This device is an ingested material that transiently occupies space in the stomach. The device passes from the body via the natural gastrointestinal tract.

(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 for its intended use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

(i) Performance bench testing in a simulated use model must evaluate device disintegration and device hydration state throughout the gastrointestinal tract;

(ii) Bioburden and moisture content assessments must evaluate device infection risk throughout the labeled shelf life; and

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

(3) Clinical performance testing must demonstrate the device performs as intended and evaluate the following:

(i) Weight change;

(ii) All adverse events, including obstruction, dilation, diarrhea, constipation, and dehydration; and

(iii) Interaction with representative medications.

(4) Physician and patient device labeling must state:

(i) The clinical benefit of the device as assessed by using percent total body weight loss;

(ii) Treatment must be offered in combination with diet and exercise;

(iii) Instructions on how to use the device as intended including how to avoid interaction with medication; and

(iv) The shelf life of the device.

[86 FR 70372, Dec. 10, 2021]

§ 876.5985 Enzyme packed cartridge.

(a) *Identification.* An enzyme packed cartridge is an *ex vivo* prescription device that is used in enzymatic hydrolysis of macronutrients into their essential nutrient forms at the time of delivery. The device consists of an outer casing containing an inert polymer with a covalently bound enzyme 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

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