FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 21 CFR 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 is revised to read as follows:

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

■ 2. Add § 864.3700 to subpart D to read as follows:

§ 864.3700 Whole slide imaging system.

(a) *Identification.* The whole slide imaging system is an automated digital slide creation, viewing, and management system intended as an aid to the pathologist to review and interpret digital images of surgical pathology slides. The system generates digital images that would otherwise be appropriate for manual visualization by conventional light microscopy.

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

(1) Premarket notification submissions must include the following information:

(i) The indications for use must specify the tissue specimen that is intended to be used with the whole slide imaging system and the components of the system.

(ii) A detailed description of the device and bench testing results at the component level, including for the following, as appropriate:

(A) Slide feeder;

(B) Light source;

(C) Imaging optics;

(D) Mechanical scanner movement;

(E) Digital imaging sensor;

(F) Image processing software;

(G) Image composition techniques;

(H) Image file formats;

(I) Image review manipulation software;

(J) Computer environment; and

(K) Display system.

(iii) Detailed bench testing and results at the system level, including for the following, as appropriate:

(A) Color reproducibility;

(B) Spatial resolution;

(C) Focusing test;

(D) Whole slide tissue coverage;

(E) Stitching error; and

(F) Turnaround time.

(iv) Detailed information demonstrating the performance characteristics of the device, including, as appropriate:

(A) Precision to evaluate intra-system and inter-system precision using a comprehensive set of clinical specimens with defined, clinically relevant histologic features from various organ systems and diseases. Multiple whole slide imaging systems, multiple sites, and multiple readers must be included.

(B) Reproducibility data to evaluate inter-site variability using a comprehensive set of clinical specimens with defined, clinically relevant histologic features from various organ systems and diseases. Multiple whole slide imaging systems, multiple sites, and multiple readers must be included.

(C) Data from a clinical study to demonstrate that viewing, reviewing, and diagnosing digital images of surgical pathology slides prepared from tissue slides using the whole slide imaging system is non-inferior to using an optical microscope. The study should evaluate the difference in major discordance rates between manual digital (MD) and manual optical (MO) modalities when compared to the reference (*e.g.,* main sign-out diagnosis).

(D) A detailed human factor engineering process must be used to evaluate the whole slide imaging system user interface(s).

(2) Labeling compliant with 21 CFR 809.10(b) must include the following:

(i) The intended use statement must include the information described in paragraph (b)(1)(i) of this section, as applicable, and a statement that reads, ''It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this device.''

(ii) A description of the technical studies and the summary of results, including those that relate to paragraphs (b)(1)(ii) and (iii) of this section, as appropriate.

(iii) A description of the performance studies and the summary of results, including those that relate to paragraph (b)(1)(iv) of this section, as appropriate.

(iv) A limiting statement that specifies that pathologists should exercise professional judgment in each clinical situation and examine the glass slides by conventional microscopy if there is doubt about the ability to accurately render an interpretation using this device alone.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28262 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2017–N–6596]

Medical Devices; General and Plastic Surgery Devices; Classification of the Irrigating Wound Retractor Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the irrigating wound retractor device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the irrigating wound retractor device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective January 2, 2018. The classification was applicable on December 16, 2016.

FOR FURTHER INFORMATION CONTACT: Terrell Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2502, Silver Spring, MD 20993–0002, 301–796–6299, *terrell.cunningham@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the irrigating wound retractor device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 13, 2015, Prescient Surgical submitted a request for De Novo classification of the CleanCision™ Wound Retraction and Protection System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 16, 2016, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4371. We have named the generic type of device irrigating wound retractor device, and it is identified as a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—IRRIGATING WOUND RETRACTOR DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Tissue or wound damage	Non-clinical performance testing, Shelf life testing, and Labeling.

TABLE 1—IRRIGATING WOUND RETRACTOR DEVICE RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Infection	Sterilization validation, Non-clinical performance testing, Shelf life testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, irrigating wound retractor devices are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.4371 to subpart E to read as follows:

§ 878.4371 Irrigating wound retractor device.

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Device size or incision length range;

(ii) Method of sterilization;

(iii) Flammability classification;

(iv) Non-pyrogenic;

(v) Shelf life; and

(vi) Maximum flow rate and suction pressure.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28255 Filed 12–29–17; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9829]

RIN 1545–BN77

Election Out of the Centralized Partnership Audit Regime

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations regarding the implementation of certain portions of section 1101 of the Bipartisan Budget Act of 2015 (BBA), which was enacted into law on November 2, 2015. Section 1101 of the BBA repeals the current rules governing partnership audits and replaces them with a new centralized partnership audit regime that, in general, assesses and collects tax at the partnership level. This document provides final regulations for electing out of the centralized partnership audit regime. The final regulations affect partnerships for taxable years beginning after December 31, 2017.