

**§ 870.1251 Temporary catheter for embolic protection during transcatheter intracardiac procedures.**

(a) *Identification.* This device is a single use percutaneous catheter system that has (a) blood filter(s) at the distal end. This device is indicated for use while performing transcatheter intracardiac procedures. The device is used to filter blood in a manner that may prevent embolic material (thrombus/debris) from the transcatheter intracardiac procedure from traveling towards the cerebral circulation.

(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) Simulated-use testing in a clinically relevant bench anatomic model to assess the following:

(A) Delivery, deployment, and retrieval, including quantifying deployment and retrieval forces, and procedural time; and

(B) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(ii) Tensile strengths of joints and components, tip flexibility, torque strength, torque response, and kink resistance.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Characterization and verification of all dimensions.

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

(i) Delivery, deployment, and retrieval, including quantifying procedural time.

(ii) Device compatibility and lack of interference with the transcatheter intracardiac procedure and device.

(iii) Flow characteristics.

(A) The ability of the filter to not impede blood flow.

(B) The amount of time the filter can be deployed in position and/or retrieved from its location without disrupting blood flow.

(iv) Gross pathology and histopathology assessing vascular injury and downstream embolization.

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

(6) Labeling for the device must include:

(i) Instructions for use;

(ii) Compatible transcatheter intracardiac procedure devices;

(iii) A detailed summary of the clinical testing conducted; and

(iv) A shelf life and storage conditions.

(7) Clinical performance testing must demonstrate:

(i) The ability to safely deliver, deploy, and remove the device;

(ii) The ability of the device to filter embolic material while not impeding blood flow;

(iii) Secure positioning and stability of the position throughout the transcatheter intracardiac procedure; and

(iv) Evaluation of all adverse events including death, stroke, and vascular injury.

Dated: January 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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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 30, 2018. The classification was applicable on December 20, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Steven Elliott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2565, Silver Spring, MD 20993-0002, 301-796-5285, [steven.elliott@fda.hhs.gov](mailto:steven.elliott@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the surgical smoke precipitator 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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 878**

**[Docket No. FDA-2017-N-6598]**

**Medical Devices; General and Plastic Surgery Devices; Classification of the Surgical Smoke Precipitator**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the surgical smoke precipitator 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 surgical smoke precipitator'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

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 May 26, 2015, Alesi Surgical submitted a request for De Novo classification of the Ultravision™ Visual Field Clearing 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 20, 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 878.5050. We have named the generic type of device surgical smoke precipitator, and it is identified as a prescription device intended for clearance of the visual field by precipitation of surgical smoke and other aerosolized particulate matter created during laparoscopic surgery.

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—SURGICAL SMOKE PRECIPITATOR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Electrical shock .....	Electrical safety testing and Labeling.
Electromagnetic interference with other devices .....	Electromagnetic compatibility testing and Labeling.
Infection .....	Sterilization validation, Shelf-life validation, and Labeling.
Adverse tissue reaction .....	Biocompatibility evaluation.
Tissue injury .....	Animal testing; Software verification, validation, and hazard analysis; 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, surgical smoke precipitators 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, 360l, 371.

- 2. Add § 878.5050 to subpart F to read as follows:

### § 878.5050 Surgical smoke precipitator.

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Labeling must identify the following:

- (i) Detailed instructions for use.
- (ii) Electrical safety and electromagnetic compatibility information.

(iii) A shelf life.

Dated: January 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF STATE

### 22 CFR Part 51

[Public Notice: 9867]

RIN 1400-AE01

### Passports: Service Passports

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** This rule finalizes the interim final rule from the Department of State that established a new service passport, which may be approved for certain non-personal services contractors who travel abroad in support of and pursuant to a contract with the U.S. government. The Department received no public comments in response to the rule.

**DATES:** Effective January 30, 2018.

### FOR FURTHER INFORMATION CONTACT:

Sitara Kedilaya, Attorney-Adviser,  
*PassportRules@state.gov*, (202) 485-6500.

**SUPPLEMENTARY INFORMATION:** On September 30, 2016, the Department published an interim final rule amending 22 CFR part 51, to create a “service passport” that would be used by non-personal services contractors to carry out critical security, maintenance and other functions on behalf of the U.S. government. As noted in the interim final rule, the Department estimates that this rulemaking will affect approximately 1,000 non-personal services contractors per year. Further information concerning the rationale for this rule can be found in the interim final rule.

The Department provided 60 days for the public to comment on this rule. This period expired on November 29, 2016. The Department received no public comments.

The Regulatory Findings included with the interim final rule are incorporated herein. This rule is not an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

### List of Subjects in 22 CFR Part 51

Administrative practice and procedure, Drug traffic control, Passports and visas, Reporting and recordkeeping requirements.

## PART 51—PASSPORTS

■ Accordingly, the interim final rule amending 22 CFR part 51, which was published at 81 FR 67156 on September 30, 2016, is adopted as a final rule without change.

**Carl C. Risch,**

*Assistant Secretary, Consular Affairs.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

[Docket No. USCG-2018-0025]

### Drawbridge Operation Regulation; Willamette River, Portland, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. The deviation is necessary to make adjustments to new equipment. This deviation allows the bridge to operate the double bascule span one side at a time, single leaf.

**DATES:** This deviation is effective without actual notice from January 30, 2018, to 11:59 p.m. on February 23, 2018. For the purposes of enforcement, actual notice will be used from 1 a.m. on January 27, 2018, through January 30, 2018.

**ADDRESSES:** The docket for this deviation, USCG-2018-0025, is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206-220-7282, email [Steven.M.Fischer@uscg.mil](mailto:Steven.M.Fischer@uscg.mil).

### SUPPLEMENTARY INFORMATION:

Multnomah County, the bridge owner, requested the Broadway Bridge be authorized to open half the span in single leaf mode to make adjustments to newly installed equipment. The Broadway Bridge crosses the Willamette River at mile 11.7, and provides 90 feet of vertical clearance above Columbia