TABLE 1—TRANSCUTANEOUS ELECTRICAL CONTINENCE DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Pain or tissue damage due to overstimulation	Non-clinical performance testing; Software verification, validation, and hazard analysis; Electrical safety testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or burn	Electrical safety testing; Software verification, validation, and hazard analysis; and Labeling.
Device failure due to electromagnetic interference	Electromagnetic compatibility (EMC) testing; software verification, validation, and hazard analysis; and Labeling.
Use error that may result in user discomfort, injury, or delay in treatment.	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. In order 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 and guidance. 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. 3501–3521). 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 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; 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 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

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

■ Add § a876.5330 to subpart F to read as follows:

§ 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.

Dated: December 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28163 Filed 12–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0573]

Medical Devices; Neurological Devices; Classification of the Diagnostic Neurosurgical Microscope Filter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the diagnostic neurosurgical microscope filter 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 diagnostic neurosurgical microscope filter'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.

DATES: This order is effective December 29, 2021. The classification was applicable on March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Daryl Kaufman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4212, Silver Spring, MD 20993–0002, 301–796–6467, *Daryl.Kaufman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the diagnostic neurosurgical microscope filter 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 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 (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

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 is required to 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 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. 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 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 April 27, 2018, Leica Microsystems AG submitted a request for De Novo classification of the Leica FL400. 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 March 28, 2019, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.4950.[1] We have named the generic type of device diagnostic neurosurgical microscope filter, and it is identified as a device intended for use during neurosurgery to visualize fluorescence and enhance visualization of tissue associated with a specific disease or condition.

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—DIAGNOSTIC NEUROSURGICAL MICROSCOPE FILTER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Incorrect or misinterpreted results, including: • False positive: Visualization of fluorescence when in fact no target fluorophore is present. • False negative: No visualization of fluorescence when in fact the target fluorophore is present.	Non-clinical performance testing, and Labeling.

[1] FDA notes that the ACTION caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

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. In order 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).

At the time of classification, diagnostic neurosurgical microscope filters 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.

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 and guidance. 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. 3501–3521). 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 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; 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 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.4950 to subpart E to read as follows:

§ 882.4950 Diagnostic neurosurgical microscope filter.

(a) *Identification.* A diagnostic neurosurgical microscope filter is a device intended for use during neurosurgery to visualize fluorescence and enhance visualization of tissue associated with a specific disease or condition.

(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, and verify and validate filter specifications and functional characteristics, including the following:

(i) Spectrum and intensity of the illumination source;

(ii) Spectrum of the excitation and emission filter modules when integrated in the surgical operating microscope;

(iii) Excitation power and power density;

(iv) Optical path loss from illumination source to objective lens or microscope camera;

(v) Homogeneity of the excitation light at the focal plane;

(vi) Fluorescence detection sensitivity;

(vii) Verification of calibration or preoperative procedures; and

(viii) If camera-based, spectral sensitivity of the camera.

(2) Labeling must include:

(i) Identification of the filter characteristics in conjunction with a compatible surgical operating microscope, to include the following:

(A) Illumination spectrum and power density; and

(B) Excitation and emission filter spectra.

(ii) Instructions for calibration or preoperative checks to ensure device functionality prior to each use;

(iii) Instructions for use with compatible surgical operating microscopes, external light sources, and cameras;

(iv) A warning that the device should only be used with fluorophores approved for use within the specified spectral ranges; and

(v) A warning that the device is not a standalone diagnostic.

Dated: December 17, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28160 Filed 12–28–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0855]

Medical Devices; Neurological Devices; Classification of the Cerebrospinal Fluid Shunt System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the cerebrospinal fluid shunt system 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 cerebrospinal fluid shunt system'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.

DATES: This order is effective December 29, 2021. The classification was applicable on August 22, 2014.

FOR FURTHER INFORMATION CONTACT: Xiaolin Zheng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2674, Silver Spring, MD 20993–0002, 301–796–2823, *Xiaolin.Zheng@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the cerebrospinal fluid shunt system 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.