section 510(m) of the FD&C Act. At this time FDA has not made this determination for cooperative powered surgical assist devices for ENT surgery. This device is therefore 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 normally 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 part 860, subpart D, regarding De Novo classification 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 management 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 874

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 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for part 874 continues to read as follows:

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

■ 2. Add § 874.4460 to subpart E to read as follows:

§ 874.4460 Cooperative powered surgical assist device for ENT surgery.

(a) *Identification.* A cooperative powered surgical assist device for ear, nose, and throat (ENT) surgery is a device that facilitates ENT surgical procedures, including instrument placement. The device works in conjunction with the surgeon's movements to assist with precise and stable positioning of an instrument while maintaining the surgeon's direct physical control of the instrument.

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

(1) Simulated-use testing must demonstrate that the device performs as intended under anticipated conditions of use to successfully assist in the indicated surgery, including:

(i) Testing in a simulated hospital environment with an anatomically relevant model;

(ii) Compatibility testing of all indicated instruments;

(iii) Human factors/usability evaluation; and

(iv) Validation of device use by surgeons, including:

(A) The user interface and controller(s);

(B) Compatibility with the ranges of surgeon-applied forces, torques, speeds, and motion; and

(C) Time required for emergency removal of the device and associated instruments in the event of power loss or device failure.

(2) Non-clinical performance testing must demonstrate hardware and system verification, including verification of critical parameters (including minimum and maximum forces, torques, speeds, and range of motion).

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

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

(5) All parts or components of the device that enter the sterile field must be demonstrated to be sterile.

(6) 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.

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

(8) Labeling must include:

(i) Identification of compatible instruments;

(ii) A statement about any training needed prior to use of the device;

(iii) A summary of all relevant performance testing, including simulated-use testing; and

(iv) Reprocessing instructions for reusable device components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18429 Filed 9–9–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2026–N–9908]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Implanted Tibial Electrical Urinary Continence Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implanted tibial electrical urinary continence 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 classification of the implanted tibial electrical urinary continence device. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 September 10, 2026. The classification was applicable on August 16, 2023.

FOR FURTHER INFORMATION CONTACT: Sharon Andrews, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2640, Silver Spring, MD 20993–0002, 301–796–6529, *Sharon.Andrews@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the implanted tibial electrical urinary continence device into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 device 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 (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (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 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 section 513(f)(2)(B)(i) of the FD&C Act). 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 section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 5, 2022, FDA received BlueWind Medical Ltd.'s request for De Novo classification of the Revi 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 the safety and effectiveness of the device, 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 section 513(a)(1)(B) of the FD&C Act). 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 August 16, 2023, 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 876.5305.[1] We have named the generic type of device ''implanted tibial electrical urinary continence device,'' and it is identified as an implanted prescription device that receives power from a non-implanted external power source to provide electrical stimulation of the tibial nerve in proximity to the ankle. The device is intended for the treatment of overactive bladder related symptoms of urge urinary incontinence, urinary urgency, urinary frequency, and nocturia.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR IMPLANTED TIBIAL ELECTRICAL URINARY CONTINENCE DEVICES

Identified risks to health	Mitigation measures
Overstimulation leading to nerve/tissue damage	Non-clinical performance testing; Electromagnetic compatibility testing; Electrical safety testing; Software verification, validation, and hazard analysis; Wireless coexistence testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation; and Labeling.
Infection	Sterilization validation; Shelf-life 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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR IMPLANTED TIBIAL ELECTRICAL URINARY CONTINENCE DEVICES—Continued

Identified risks to health	Mitigation measures
Thermal injury	Non-clinical performance testing; Thermal safety testing; and Electrical safety testing.
Interference with other medical devices	Electromagnetic compatibility testing; Magnetic resonance compatibility testing; Electrical safety testing; Software verification, validation and hazard analysis; Wireless coexistence testing; and Labeling.
Pain and discomfort	Non-clinical performance testing; Electrical safety testing; and Labeling.
Electrical shock or stimulation of non-target tissue	Electrical safety testing; Electromagnetic compatibility testing; and Labeling.
Mechanical injury to device or tissue/nerves	Non-clinical performance testing; and Labeling.
Undesired fluid retention due to use in inappropriate population	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. 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 final order.

At the time of classification, implanted tibial electrical urinary continence 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.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for implanted tibial electrical urinary continence devices. This device is therefore 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 normally 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 part 860, subpart D, regarding De Novo classification 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 management 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.

■ 2. Add § 876.5305 to subpart F to read as follows:

§ 876.5305 Implanted tibial electrical urinary continence device.

(a) *Identification.* An implanted tibial electrical urinary continence device is an implanted prescription device that receives power from a non-implanted external power source to provide electrical stimulation of the tibial nerve in proximity to the ankle. The device is intended for the treatment of overactive bladder related symptoms of urge urinary incontinence, urinary urgency, urinary frequency, and nocturia.

(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 testing must be conducted:

(i) Electrical performance testing of the device must be conducted to validate the specified electrical output and duration of stimulation of the device; and

(ii) Testing must verify the implant can withstand clinically relevant forces during and after implantation.

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

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

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

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

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

(7) Performance testing must evaluate the compatibility of the device in a magnetic resonance environment.

(8) Labeling for the device must include:

(i) A contraindication against use during pregnancy;

(ii) A contraindication against using the device in men who have Benign Prostatic Hyperplasia (BPH) or other lower urinary tract obstructions;

(iii) A detailed summary of the device technical parameters and the typical course of treatment;

(iv) Device- and procedure-related adverse events pertinent to use of the device; and

(v) A shelf life for any sterile components.

(9) Patient labeling must include:

(i) Post-operative care instructions to avoid infection and inflammation of the surgical site;

(ii) Instructions to avoid overstimulation related nerve and tissue damage;

(iii) Instructions to avoid mechanical injuries to nerve and tissue caused by the implanted component;

(iv) Instructions for reprocessing/cleaning of any reusable components;

(v) Clinical performance reported by relevant subgroups;

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

(vii) Information on the typical course of treatment;

(viii) Instructions to avoid pain and discomfort; and

(ix) Instructions to avoid interference with other medical devices.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18428 Filed 9–9–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2026–N–9909]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Whole Room Microbial Reduction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the whole room microbial reduction 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 classification of the whole room microbial reduction device. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 September 10, 2026. The classification was applicable on September 1, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher Dugard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4640, Silver Spring, MD 20993–0002, 240–402–6031, *Christopher.Dugard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the whole room microbial reduction device into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 device 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 (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (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 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 section 513(f)(2)(B)(i) of the FD&C Act). 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 section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 1, 2023, FDA received Xenex Disinfection Services, Inc.'s request for De Novo classification of the LightStrike+ device. 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