the sample has to yield to be interpretable as a valid result).

(iv) Limiting statements indicating that:

(A) Results are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. The test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence.

(B) Device results are intended to be followed up according to the latest professional guidelines (*e.g.,* recommendations from the Centers for Disease Control and Prevention) for the diagnosis of Zika virus infection.

(C) Negative test results do not preclude the possibility of Zika virus infection, past or present.

(D) Specimens can result in false negative results on the device if collected outside of the appropriate response window for specific Zika virus antigens or antibodies, as determined by scientific evidence (*e.g.,* for IgM <7 days post symptom onset (pso) or risk of exposure and if collected past 84 days pso).

(v) Detailed instructions for use that minimize the risk of generating a false positive or false negative result (*e.g.,* co-testing of other matrices).

(2) Design verification and validation must include:

(i) A detailed device description, including all device parts (*e.g.,* Zika antigen target, other flavivirus antigen target, capture antibodies), instrument requirements, ancillary reagents required but not provided, and the technological characteristics, including all pre-analytical methods for specimen processing.

(ii) Detailed documentation and results from analytical performance studies including: characterization of the cut-off(s), analytical sensitivity to a standardized reference material that FDA has determined is appropriate (*e.g.,* World Health Organization reference standard or the Centers for Disease Control and Prevention reference standard), class specificity for human antibodies (*e.g.,* IgM or IgG), analytical specificity (cross reactivity including cross reactivity to other flaviviruses), interference, carryover/cross contamination, specimen stability, hook effect (if applicable), matrix equivalency (if applicable), freeze-thaw studies (if applicable), and reproducibility.

(iii) Detailed documentation and results from clinical studies, including the clinical study protocol (with a description of the testing algorithm and results interpretation table), detailed clinical study report, including line data of the clinical study results, and other appropriate statistical analysis. The samples used in the clinical study must be collected from subjects representative of the full spectrum of the intended use population (*e.g.,* endemic and non-endemic regions if both are indicated).

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09639 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2025–N–1163]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Temporarily-Placed Urethral Opening System for Symptoms of Benign Prostatic Hyperplasia

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia 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 temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia'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 May 29, 2025. The classification was applicable on February 25, 2020.

FOR FURTHER INFORMATION CONTACT: Mark Kreitz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2630, Silver Spring, MD 20993–0002, 301–796–7019, *Mark.Kreitz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia 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 (see 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 application 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 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 (21 U.S.C. 360c(a)(1)). 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 April 2, 2019, FDA received Medi-Tate Ltd.'s request for De Novo classification of the iTind 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 February 25, 2020, 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 876.5510.[1] We have named the generic type of device temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia, and it is identified as a prescription use device that is inserted transurethrally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men.

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—TEMPORARILY-PLACED URETHRAL OPENING SYSTEM FOR SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Clinical performance testing, Biocompatibility evaluation, and Labeling.
Infection	Clinical performance testing, Sterilization validation, Shelf life testing, and Labeling.
Untreated symptoms due to device deployment failure	Clinical performance testing, Non-clinical performance testing, Shelf life testing, and Labeling.
Bleeding, perforation, trauma, obstruction, incontinence, dysuria, urgency due to device failure or difficult removal.	Clinical performance testing, Non-clinical performance testing, Shelf life testing, 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, temporarily-placed urethral opening systems for symptoms of benign prostatic hyperplasia 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 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

[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.

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.

■ 2. Add § 876.5510 to subpart F to read as follows:

§ 876.5510 Temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia.

(a) *Identification.* A temporarily-placed urethral opening system for symptoms of benign prostatic hyperplasia (BPH) is a prescription use device that is inserted transurethrally and deployed at the prostate. The implant is designed to increase prostatic urethral patency by increasing prostatic opening. It is intended for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men.

(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 improvement in urinary outflow symptoms and document the adverse event profile.

(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, package integrity, and device functionality 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 performance characteristics must be tested:

(i) Deployment and removal; and

(ii) Mechanical strength.

(6) Labeling must include:

(i) Instructions for use, including the recommended training for safe use of the device;

(ii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events; and

(iii) A shelf life.

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09640 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2025–0441]

Special Local Regulations; Marine Events Within the Fifth Coast Guard District; Washington, DC Dragon Boat Festival

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for a recurring marine event in the Fifth Coast Guard District. This regulation applies to the Washington, DC Dragon Boat Festival. This action is intended to restrict vessel traffic in a portion of the Upper Potomac River near Washington, DC, in order to provide for the safety of life on navigable waters during the event.

DATES: On May 31, 2025, from 7:30 a.m. until 6:30 p.m., the regulations in 33 CFR 100.501 will be enforced for the location identified in table 2 to 33 CFR 100.501(i)(2) for the event denominated as ''Washington, DC Dragon Boat Festival.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRMarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.501 for the Washington, DC Dragon Boat Festival regulated area from 7:30 a.m. to 6:30 p.m. on May 31, 2025. This action is being taken to provide for the safety of life on navigable waterways during this event. As stated in footnote one to table 2 to paragraph (i)(2), the enforcement dates and times for each of the listed events in the table are subject to change. Due to inclement weather, the Washington, DC Dragon Boat Festival has been rescheduled (for this year only) from the third weekend in May to May 31, 2025, for a one-day event. Our regulation for marine events within the Fifth Coast Guard District, § 100.501, specifies the location of the regulated area for the Washington, DC Dragon Boat Festival, which encompasses portions of the navigable waters of the Upper Potomac River. During the enforcement periods, as reflected in § 100.100(c), the operator of a vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register,** the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcast.

Dated: May 21, 2025.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2025–09644 Filed 5–28–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0385]

RIN 1625–AA00

Safety Zone; Edgewater Beach, Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of Lake Erie offshore Edgewater Beach in Cleveland, Ohio. This action is necessary to provide for the safety of life on these navigable waters during the US Rowing Beach Sprints Mini Camp. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port,