premarket notification requirements under section 510(k) of the FD&C Act.

III. 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. 3501–3521). 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 have been approved under OMB control number 0910–0073, 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 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Add § 866.3975 to subpart D to read as follows:

§ 866.3975 Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis.

(a) *Identification.* A device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis is a qualitative in vitro diagnostic device intended for the detection of microbial nucleic acid sequences in vaginal specimens collected from patients with signs and symptoms of vaginitis or bacterial vaginosis. This device is intended to aid in the diagnosis of vaginitis or bacterial vaginosis when used in conjunction with clinical signs and symptoms and other laboratory findings.

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

(1) Design verification and validation must include:

(i) Documentation with a detailed device description of device components; ancillary reagents required but not provided; and explanation of the methodology including primer/probe sequence, design, and rationale for sequence selection.

(ii)Documentation with information that demonstrates the performance characteristics of the device, including:

(A)Limit of Detection;

(B)Precision (reproductivity);

(C)Analytical specificity;

(D) Analytical reactivity (inclusivity);

(E) Specimen stability; and

(F) Effects of interfering substances.

(iii) Detailed documentation from a prospective clinical study. As appropriate to the intended use, the prospective clinical study must be performed on an appropriate study population, including women of various ages and ethnicities. The prospective clinical study must compare the device performance to results obtained from well-accepted comparator methods.

(iv) Detailed documentation for device software, including software applications and hardware-based devices that incorporate software.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) A detailed explanation of the interpretation of results and acceptance criteria;

(ii) For devices with an intended use that includes detection of nucleic acid sequences from bacteria associated with bacterial vaginosis, clinical performance stratified by patient demographics such as race, ethnicity, age, and pregnancy status.

(iii) For devices with an intended use that includes detection of nucleic acid sequences from bacteria associated with bacterial vaginosis, a summary of device results in an asymptomatic population with demographic characteristics appropriate to the intended use population.

(iv) For devices with an intended use that includes detection of either Candida species or bacteria associated with bacterial vaginosis, a limitation that *Candida* species and bacterial compositions associated with bacterial vaginosis can be present as part of normal vaginal flora and results should be considered in conjunction with available clinical information.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16030 Filed 8–20–25; 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–2823]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Laparoscopic Gastrointestinal Sizing Tool

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment: final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the laparoscopic gastrointestinal sizing tool 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 classification of the laparoscopic gastrointestinal sizing tool. We are taking this action because we have determined that classifying the device into class II 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 August 21, 2025. The classification was applicable on February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Pramodh Kariyawasam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2536, Silver Spring, MD 20993–0002, 301–348–1911, *Pramodh.Kariyawasam@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the laparoscopic gastrointestinal sizing tool as class II (special controls), which we have determined will provide a

reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based on the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days of announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days of announcing the classification.

II. Accessory Classification

On November 12, 2019, FDA received Torax Medical Inc.'s request for accessory classification of the LINX Reflux Management System—Esophagus Sizing Tool. 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 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 February 4, 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 876.5360.[1] We have named the generic type of device ''laparoscopic gastrointestinal sizing tool,'' and it is identified as a prescription use device intended for laparoscopically measuring an extraluminal dimensional parameter of the indicated gastrointestinal organs.

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—LAPAROSCOPIC GASTROINTESTINAL SIZING TOOL RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Longer procedure time due to: • Use error • Inaccuracy of the size markers • Breaking • Unintentional separation of components	Non-clinical performance testing; Shelf life testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation; and Labeling.
Retained foreign body due to: • Breaking • Unintentional separation of components	Non-clinical performance testing; Shelf life testing; and Labeling.
Infection	Non-clinical performance testing; Shelf life testing; Sterility and/or reprocessing validation; 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 final order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act (21 U.S.C. 360(k)).

At the time of classification, laparoscopic gastrointestinal sizing tools are for prescription use only. Prescription devices are exempt from the requirement for adequate directions

[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.

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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. At a future date, we may publish a separate notice in the **Federal Register** announcing our intent to exempt this device type.

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 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in the guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; and the collections of information in 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 § 876.5360 to subpart F to read as follows:

§ 876.5360 Laparoscopic gastrointestinal sizing tool.

(a) *Identification.* A laparoscopic gastrointestinal sizing tool is a prescription use device intended for laparoscopically measuring an extraluminal dimensional parameter of the indicated gastrointestinal organs.

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

(1) Performance testing must demonstrate that the sizing tool performs as intended under anticipated conditions of use. Performance testing must include the following:

(i) Trocar compatibility, which includes shaft bending force characterization;

(ii) Joint strength tensile testing;

(iii) Distal loop extension/retraction force characterization;

(iv) Material selection analysis, which includes corrosion and visual inspection; and

(v) Accuracy of the dimensional measurement.

(2) Performance testing must support the sterility and/or reprocessing and shelf life of the patient-contacting components of the device.

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

(4) Labeling of the device must include the following:

(i) A statement regarding metal allergies if the device is made from metallic components;

(ii) Specific instructions for proper device use including information regarding the following:

(A) Inspection of device prior to use;

(B) Surgical access techniques or methodologies;

(C) Instructions for avoiding structural damage to vagus nerve bundle;

(D) Trocar compatibility;

(E) Sizing methodology; and

(F) Minimum and maximum dimensional parameters that the device is capable of measuring.

(iii) Identification of the associated parent device with which the sizing tool has been demonstrated to be compatible; and

(iv) An expiration date.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16041 Filed 8–20–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2025–N–2523]

Medical Devices; Orthopedic Devices; Classification of Orthopedic Manual Surgical Instrumentation for Use With Non-Fusion Spinous Process Spacer Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices 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 orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices. We are taking this action because we have determined that classifying the device into class II 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 August 21, 2025. The classification was applicable on July 6, 2020.

FOR FURTHER INFORMATION CONTACT: Anne Talley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G225, Silver Spring, MD 20993–0002, 240–402–6536, *Anne.Talley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified orthopedic manual surgical instrumentation for use with non-fusion spinous process spacer devices as class II (special controls), which we have determined will provide a reasonable