



February 4, 2020

Torax Medical Inc.
Christine Erickson
Senior Regulatory Affairs Program Lead
4188 Lexington Ave N.
Shoreview, MN 55126

Re: Q191422/S001
LINX Reflux Management System – Esophagus Sizing Tool
Evaluation of Accessory Classification Under Section 513(f)(6) –
Accessory Classification Request
Regulation Number: 21 CFR 876.5360
Regulation Name: Laparoscopic gastrointestinal sizing tool
Regulatory Classification: II
Code: QJN
Dated: November 11, 2019
Received: November 12, 2019

Dear Ms. Erickson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification request for classification of the LINX Reflux Management System – Esophagus Sizing Tool, a prescription device under 21 CFR 801.109 that is intended to measure the esophagus to support, supplement, and/or augment the performance of one or more parent devices.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the LINX Reflux Management System – Esophagus Sizing Tool and substantially equivalent devices of this generic type, into class II under the generic name laparoscopic gastrointestinal sizing tool.

FDA identifies this generic type of device as:

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

Section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017 and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon 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 proper 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 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 announcing the classification.

FDA received your Accessory Classification request on November 12, 2019 to classify the LINX Reflux Management System – Esophagus Sizing Tool into class II under section 513(f)(6)(D)(ii) of the FD&C Act. To classify the LINX Reflux Management System – Esophagus Sizing Tool into class I or II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification request FDA has determined that LINX Reflux Management System – Esophagus Sizing Tool intended to measure the esophagus to support, supplement, and/or augment the performance of one or more parent devices can be classified in class II with the establishment of special controls. FDA has determined that class II (special controls) provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Longer procedure time due to: <ul style="list-style-type: none"> • Use error • Inaccuracy of the size markers • Breaking • Unintentional Separation of Components 	Non-clinical performance testing Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Retained foreign body due to: <ul style="list-style-type: none"> • Breaking • Unintentional separation of Components 	Non-clinical performance testing Shelf life testing Labeling
Infection	Non-clinical performance testing Shelf life testing Sterility and/or reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the laparoscopic gastrointestinal sizing tool is subject to the following special controls:

- 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;
 - 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
 - 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.
 - iv. An expiration date.

Section 510(m)(2) 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 the safety and effectiveness of the device type. We believe this may be such a device type, and a notice of intent to exempt the device type from premarket notification requirements may appear in the same issue of the **Federal Register** in which we announce this classification order.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Pramodh Kariyawasam at (301) 348-1911.

Sincerely,

/s/

Benjamin R. Fisher, Ph.D.

Director

OHT3: Office of GastroRenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health