February 9, 2023

Torax Medical Inc.
Brian Godwin
Associate Director, Regulatory Affairs
4188 Lexington Avenue North
Shoreview, MN 55126

Re: K230089
Trade/Device Name: ETHICON LINX® Esophagus Sizing Tool
Regulation Number: 21 CFR 876.5360
Regulation Name: Laparoscopic gastrointestinal sizing tool
Regulatory Class: Class II
Product Code: QJN
Dated: January 11, 2023
Received: January 12, 2023

Dear Brian Godwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the

Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230089

Device Name
ETHICON LINX® Esophagus Sizing Tool

Indications for Use *(Describe)*

The ETHICON LINX® Esophagus Sizing Tool for the LINX Reflux Management System is a laparoscopic accessory used to estimate the appropriate size LINX® device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information:	Torax Medical Inc. 4188 Lexington Avenue North Shoreview, MN 55126
Application Correspondent:	Brian Godwin Associate Director, Regulatory Affairs Torax Medical Inc. Telephone: (513) 337-3623 Email: bgodwin@its.jnj.com
Date Prepared:	10 January 2023
Device Trade Name:	ETHICON LINX® Esophagus Sizing Tool
Device Common Name:	Laparoscopic gastrointestinal sizing tool
Classification Regulation:	21 CFR 876.5360
Device Class:	II
Panel:	78, Gastroenterology and Urology
Classification (Product) Code:	QJN
Predicate Device:	ETHICON LINX® Esophagus Sizing Tool K201035, cleared 09 July 2020

Device Description

The LINX Esophagus Sizing Tool is a sterile, single-use device that is used as an accessory to the LINX Reflux Management System (packaged separately). The device has a soft, circular curved tip that is actuated by coaxial tubes via a handset. The handset contains numerical indicators that correspond to the size range of the LINX implant.

Indications for Use

The ETHICON LINX® Esophagus Sizing Tool for the LINX Reflux Management System is a laparoscopic accessory used to estimate the appropriate size LINX® device.

Technological Characteristics

The design and performance of the LINX Esophagus Sizing Tool is based on the currently marketed predicate device. The changes described in this submission do not affect the intended use of the device or alter the fundamental scientific technology of the device. The clinical, technical, and biological parameters of the subject device are the same as the predicate. The technique used for determining the appropriate LINX implant device size remains unchanged between the subject and predicate; however, the Instructions for Use have been updated for clarity on implanting based on current clinical practice, reflected in the edits below.

8. *Retract the distal white loop until the loop rests comfortably around the esophagus but does not compress the esophagus and can move with shaft rotation. Note the*

number indicated by the numerical markings on the handset. This gives the approximate size of the esophagus in "bead-size."

9. *Using the readout provided in Step 8 and considering anatomic and physiological considerations, choose the implant size that best suits the patient's unique clinical scenario. When a readout is between sizes, it is recommended to use the larger of the sizes.*

The subject and predicate devices are both manually powered and not powered by an outside energy source. Neither the subject device nor predicate device uses software.

Performance Data

No laboratory evaluations or bench testing were conducted to demonstrate that the LINX Esophagus Sizing Tool is equivalent to the predicate.

Sterilization & Shelf Life
There have been no changes to the sterilization parameters or shelf life of the LINX Esophagus Sizing Tool.

Biocompatibility & Pyrogenicity
There have been no changes to the materials used in the LINX Esophagus Sizing Tool.

Bench Testing
No bench tests were performed to support substantial equivalence to the predicate.

Animal Testing
No animal tests were performed to demonstrate substantial equivalence to the predicate.

Clinical Studies
This premarket notification does not rely on human clinical data to demonstrate substantial equivalence.

Conclusion

The risk profile of the subject device has not changed as a result of the described changes while having the same intended use as the predicate device; furthermore, the performance of the subject device is consistent with the predicate device and does not raise any new questions of safety and effectiveness.