July 9, 2020

Torax Medical, Inc.
Joseph Ciccone
Associate Director, Regulatory Affairs
4188 Lexington Avenue, N
Shoreview, MN 55126

Re: K201035
Trade/Device Name: ETHICON Linx Esophagus Sizing Tool
Regulation Number: 21 CFR 876.5360
Regulation Name: Laparoscopic Gastrointestinal Sizing Tool
Regulatory Class: II
Product Code: QJN
Dated: April 17, 2020
Received: April 20, 2020

Dear Joseph Ciccone:

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,

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201035

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.

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510(k) Summary

Submitter Information:
Torax Medical Inc.
4188 Lexington Avenue North
Shoreview, MN 55126

Application Correspondent:
Joseph Ciccone
Associate Director, Regulatory Affairs
Torax Medical Inc.
Telephone: (908) 218-2853
Email: jciccon1@its.jnj.com

Date Prepared: July 9, 2020

Device Trade Name: ETHICON Linx® Esophagus Sizing Tool
Regulation 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: Q191422/S001

Device Description

The ETHICON Linx Esophagus Sizing Tool (also referred to as LINX® Esophagus Sizing Tool, hereafter) is an accessory to the LINX Reflux Management System implant (packaged separately). The LINX Esophagus Sizing Tool is a single use disposable device that is provided sterile. The LINX Esophagus Sizing Tool is a laparoscopic instrument and has two ends – the handset, considered the proximal end and not intended for patient contact, and the shaft with protruding circular curved tip, considered the distal end and is intended for limited contact with the patient. The handset is designed with a thumbwheel for one-handed operation. When actuated, the thumbwheel advances and retracts the soft polymeric circular curved tip of the distal end. The handle has a numerical indicator which directly correlates with the number of beads for the range of sizes of the approved LINX implant device. The shaft and distal end of the circular curved tip each have a magnet which allows the user to create a loop and attach the magnets to each other. Once the magnets are attached, the user retracts slack from the soft distal end until the loop is in circumferential contact with the esophagus. The LINX Esophagus Sizing Tool is utilized at the time of implant to associate the esophagus size to a LINX implant device size to aid in guiding the user into choosing an appropriately sized LINX implant device.

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 designs. 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. The modifications to the design were made to enhance comfortability and ease of use of the subject device.

The primary differences in the devices include design and operation of the handle and shaft stiffness. The 510(k)-subject device was designed for one-handed operation, while the predicate requires two hands. Control for extending and retracting the distal loop of the 510(k)-subject device is accomplished with the use of a thumbwheel; the predicate device requires the user to depress the end of the handle to extend the distal loop; retraction occurs by actuating a side-mounted lever. The sizing indicator on the handle of the 510(k)-subject device is different from the predicate - the subject device's numerical indicator displays 13-18, the predicate presents 11-18. The shaft of 510(k)-subject device is more rigid, or stiff, than the predicate. Other differences include some materials used in the construct of the devices. All materials used in the 510(k)-subject device are commonly used in medical devices.

Performance Data

Performance data demonstrates that the subject device is substantially equivalent to the predicate device and any differences between the devices were found not to affect safety or performance. The following were performed to demonstrate substantial equivalence to the predicate:

Sterilization & Shelf Life
The 510(k)-subject device will be sterilized by Cobalt 60 irradiation. The device will be validated to achieve 10^{-6} sterility assurance level (SAL).

The LINX Esophagus Sizing Tool has a validated shelf life based on results of an accelerated aging stability study.

Biocompatibility & Pyrogenicity
The biocompatibility of materials used in the LINX Esophagus Sizing Tool were evaluated based on ISO 10993-1:2018 - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing and on FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued on June 16, 2016.

The 510(k)-subject materials evaluated were determined to be non-pyrogenic.

Bench Testing
The following bench testing was performed to demonstrate that the ETHICON Linx Esophagus Sizing Tool performs as intended under anticipated conditions of use:

- Trocar compatibility, which includes shaft bending force characterization;
- Joint strength tensile testing;
- Distal loop extension/retraction force characterization;
- Material selection analysis, which includes corrosion and visual inspection;
- Accuracy of the dimensional measurement;
- Minimize tissue damage;
- Human factors & ease of use;
- Reliability testing.

Animal Testing
No animal tests were performed to demonstrate substantial equivalence to the predicate as it was deemed as not required.

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

Conclusion
The results of the performance testing demonstrate that the LINX Esophagus Sizing Tool is substantially equivalent to the predicate device.