March 15, 2023

Ethicon Endo-Surgery
Alicia Butler
Senior Regulatory Affairs Specialist
475 Calle C
Guaynabo, PR 00969

Re: K223760
Trade/Device Name: ECHELON LINEAR™ 60 mm Cutter (GLC60);ECHELON LINEAR™ 80mm Cutter (GLC80);ECHELON LINEAR™ 100 mm Cutter (GLC100);ECHELON LINEAR™ Cutters 60mm Blue Reload (GLCR60B);ECHELON LINEAR™ Cutters 60mm Green Reload (GLCR60G);ECHELON LINEAR™ Cutters 80mm Blue Reload (GLCR80B);ECHELON LINEAR™ Cutters 80mm Green Reload (GLCR80G);ECHELON LINEAR™ Cutters 100mm Blue Reload (GLCR100B);ECHELON LINEAR™ Cutters 100mm Green Reload (GLCR100G)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 15, 2022
Received: December 15, 2022

Dear Alicia Butler:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.03.15 08:05:38 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

Submission Number *(if known)*

Device Name

ECHELON LINEAR™ 60 mm Cutter (GLC60);
ECHELON LINEAR™ 80mm Cutter (GLC80);
ECHELON LINEAR™ 100 mm Cutter (GLC100);
ECHELON LINEAR™ Cutters 60mm Blue Reload (GLCR60B);
ECHELON LINEAR™ Cutters 60mm Green Reload (GLCR60G);
ECHELON LINEAR™ Cutters 80mm Blue Reload (GLCR80B);
ECHELON LINEAR™ Cutters 80mm Green Reload (GLCR80G);
ECHELON LINEAR™ Cutters 100mm Blue Reload (GLCR100B);
ECHELON LINEAR™ Cutters 100mm Green Reload (GLCR100G)

Indications for Use *(Describe)*

The ECHELON LINEAR™ Cutters have application in gastrointestinal, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Company: Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact: Alicia Butler
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
Phone: 513-337-1633
Email: abutler9@its.jnj.com

Date Prepared: December 15, 2022

II. SUBJECT DEVICES

Trade Names:

- ECHELON LINEAR™ 60mm Cutter and Reloads
- ECHELON LINEAR™ 80mm Cutter and Reloads
- ECHELON LINEAR™ 100mm Cutter and Reloads

Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Implantable staple (21 CFR 878.4750)
Regulatory Class: Class 2 -Staple, Implantable
Product Code: GDW

Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Surgical Stapler (21 CFR 878.4740)
Regulatory Class: Class 2 – Stapler, Surgical
Product Code: GAG

III. PREDICATE DEVICES

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Product Codes
K020779	PROXIMATE® Linear Cutters with Safety Lockout and Reloads	Devices: TLC55, TLC75, TLC10 Reloads: TCR55, TCT55, TCR75, TCT75, TCR10, TCT10

These predicates have not been Subjected to a recall related to these design modifications.

Table 5-1: ECHELON LINEAR™ Cutters Product Configuration

Subject Device Product Code	**Product Code Description**	**Staple Line Length**	**Cut Line Length**	**Subject Device Reloads**	**Predicate Device Product Code**	**Predicate K number**
GLC60	ECHELON LINEAR™ 60mm Cutter	61mm	55mm	GLCR60B GLCR60G	TLC55 Compatible Reloads: TCR55 (Blue) TRT55 (Green)	K020779
GLC80	ECHELON LINEAR™ 80mm Cutter	81mm	75mm	GLCR80B GLCR80G	TLC75 Compatible Reloads: TCR75 (Blue) TRT75 (Green)	K020779
GLC100	ECHELON LINEAR™ 100mm Cutter	101mm	95mm	GLCR100B GLCR100G	TLC10 Compatible Reloads: TCR10 TRT10	K020779

Table 5-2: Reload codes and corresponding reload color

Reloads Codes for 60mm	**Reload Codes for 80mm**	**Reload Codes for 100mm**	**Corresponding Reload Color**
GLCR60**B**	GLCR80**B**	GLCR100**B**	Blue
GLCR60**G**	GLCR80**G**	GLCR100**G**	Green

DEVICE DESCRIPTION

The ECHELON LINEAR™ Cutter delivers two, double-staggered rows of staples while simultaneously dividing the tissue between rows. The instrument has a safety lockout feature that is designed to prevent firing if either no reload or a used reload is installed. An unclamp lockout feature prevents knife exposure by allowing the instrument to open only when the Firing Knob is in the home position. A clamp lockout feature prevents closure of the jaws when the knife is not in the home position. A Staple Retaining Cap on the reload protects the staple leg points during shipping and transportation.

This device may be used on the general population for routine wound closure via stapling.

The 60 mm reload creates a 61 mm staple line and cuts tissue approximately 52 mm beyond the tissue stop.
The 80 mm reload creates an 81 mm staple line and cuts tissue approximately 72 mm beyond the tissue stop.
The 100 mm reload creates a 101 mm staple line and cuts tissue approximately 92 mm beyond the tissue stop.

The instruments are shipped without a reload and must be loaded prior to use. The instrument may be loaded eight times for a maximum of eight firings per instrument during a single procedure.

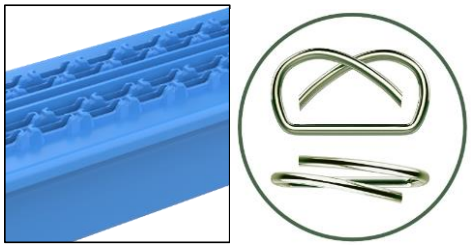
IV. INDICATIONS FOR USE

The ECHELON LINEAR™ Cutters have application in gastrointestinal, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ECHELON LINEAR™ Cutter is substantially equivalent to PROXIMATE® Linear Cutters with respect to operating principle of device and Intended Use of the device. Both the devices are sterile, single use manual devices. The key technological difference between the Subject and the predicate device is the change to the reloads with the addition of GST technology and a new 3D style anvil pocket.
The Subject device is a next generation Linear Cutter to be used in open procedures requiring a surgical stapler. To improve stapling performance, the Subject device incorporates proven GST Reload Technology, leveraged from Ethicon Endocutters, and new 3-D B-shaped final staple form into the new ECHELON LINEAR™ Cutter Reload as shown in ***illustration 5-1***.

Illustration 5-1: GST Reload Technology and 3-D Final Staple Form



GST 3-D

The Subject and predicate staplers have the following identical features:

- Indication (the compatibility with staple line reinforcement materials has not been evaluated for the Subject device and thus has been removed)
- Intended use
- Contraindications
- Materials
- MR compatibility
- Sterilization Method
- Operational principles

The following differences exist between the Subject and predicate staplers:

- Reloads: Subject device reloads contain GST technology used in Ethicon Endocutters along with a new 3D style anvil pocket. Also, only the newly designed Green and Blue reloads will be compatible with the device.
- New handle half coupling. The two device halves can be joined proximally or separated when maneuvering on tissue.
- Clamp arm that latches when the device is clamped closed and unlatches by pressing the clamp release button.
- Firing knob consists of dual foldable firing knobs that can be activated from either the left side or the right side of the assembled device.

VI. PERFORMANCE DATA:

The following performance data demonstrate that the Subject device is substantially equivalent to the predicate device and the differences between the devices were found not to affect safety or performance.

Bench Testing:

- Device Stapling Performance and Comparison to Predicate
    - Formed Staple Height (FSH)
    - Staple Form Quality (SFQ)
    - Staple Line Integrity (SLI)
- Device Functional Requirement
    - Force to Close/Clamping Force
    - Force to Fire
    - Force to Couple/Decouple Device Halves
    - Force to Press Clamp Release Button
    - Human Factor Report
- Product Characterization
    - Staple line Strength Test

Animal Testing: In-vivo testing evaluations included

- Acute Hemostasis evaluation study
- Tissue Healing response, Survival Study using both gastrointestinal and pulmonary models.

Clinical studies: The premarket submission did not rely on the assessment of clinical performance data to demonstrate device performance and equivalence.

Biocompatibility: studies were performed and confirmed that the Subject device is biocompatible for the intended patient contact profile.

Electrical Safety and Electromagnetic Compatibility: This device is not powered and therefore this does not apply.

VII. CONCLUSIONS

The conclusions of the testing criteria demonstrate that the Subject device; ECHELON LINEAR™ CUTTER performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.