February 25, 2025

Ethicon Endo- Surgery. LLC
Aysenur Huseyinoglu Erucman
Senior Regulatory Affairs Specialist
475 Calle C
Guaynabo, PR 00969

Re: K243276
Trade/Device Name: ECHELON LINEAR™ Stapler 30mm Stapler (GTX30); ECHELON LINEAR™ Stapler 60mm Stapler (GTX60); ECHELON LINEAR™ Stapler 90mm Stapler (GTX90); ECHELON LINEAR™ Stapler 3D 30mm Blue Reload (GTXR30B); ECHELON LINEAR™ Stapler 3D 30mm Green Reload (GTXR30G); ECHELON LINEAR™ Stapler 3D 60mm Blue Reload (GTXR60B); ECHELON LINEAR™ Stapler 3D 60mm Green Reload (GTXR60G); ECHELON LINEAR™ Stapler 3D 90mm Blue Reload (GTXR90B); ECHELON LINEAR™ Stapler 3D 90mm Green Reload (GTXR90G)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: October 16, 2024
Received: January 28, 2025

Dear Aysenur Huseyinoglu Erucman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2025.02.25 21:04:48 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243276

Device Name

ETHICON™ Linear Stapler 30mm Stapler (GTX30);
ETHICON™ Linear Stapler 60mm Stapler (GTX60);
ETHICON™ Linear Stapler 90mm Stapler (GTX90);
ETHICON™ Linear Stapler 3D Reload 30 mm Blue (GTXR30B);
ETHICON™ Linear Stapler 3D Reload 30mm Green (GTXR30G);
ETHICON™ Linear Stapler 3D Reload 60mm Blue (GTXR60B);
ETHICON™ Linear Stapler 3D Reload 60mm Green (GTXR60G);
ETHICON™ Linear Stapler 3D Reload 90mm Blue (GTXR90B);
ETHICON™ Linear Stapler 3D Reload 90mm Green (GTXR90G)

Indications for Use *(Describe)*

The ETHICON™ Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.

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

I. SUBMITTER

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

Contact: Aysenur Huseyinoglu Erucman
Senior Regulatory Affairs
Specialist Ethicon Endo-
Surgery, Inc.
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Date Prepared: February 25, 2025

II. Subject DEVICES

Trade Names:

- ETHICON™ Linear Stapler 30mm Stapler (GTX30)
- ETHICON™ Linear Stapler 60mm Stapler (GTX60)
- ETHICON™ Linear Stapler 90mm Stapler (GTX90)
- ETHICON™ Linear Stapler 3D Reload 30 mm Blue (GTXR30B)
- ETHICON™ Linear Stapler 3D Reload 30mm Green (GTXR30G)
- ETHICON™ Linear Stapler 3D Reload 60mm Blue (GTXR60B)
- ETHICON™ Linear Stapler 3D Reload 60mm Green (GTXR60G)
- ETHICON™ Linear Stapler 3D Reload 90mm Blue (GTXR90B)
- ETHICON™ Linear Stapler 3D Reload 90mm Green (GTXR90G)

Classification Name:	Surgical Stapler Staple, Implantable
Classification Regulation :	21 CFR878.4750 21 CFR 878.4740
Regulatory Class:	Class 2 -Staple, Implantable
Product Code:	GDW,GAG

III. Predicate DEVICES

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Model Numbers
K020779	PROXIMATE® Reloadable Linear Stapler and reloads	Devices: TX30B, TX30G, TX60B, TX60G Reloads: XR30B, XR30G, XR60B, XR60G

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

Reference Device(s):

The below reference devices were used to show equivalency to the 3D technology:

Reference Device Models

Reference Device 510(k) Number	Reference Device Name	Reference Device Model Numbers
K223760	ECHELON LINEAR™ Cutter Reloads	GLCR60B,GLCR60G,GLCR80B,GLCR80G, GLCR100B,GLCR100G
K200420	ECHELON CONTOUR™ Curved Cutter Reloads	GCR40B, GCR40G
K163523	ECHELON CIRCULAR™ Powered Stapler	CDH23P, CDH25P, CDH29P, CDH31P
K070887	ECHELON 60 Endopath Stapler, Endoscopic Linear Cutter Reload	ECR60G

ETHICON™ Linear Staplers Product Configuration

Subject Device Model Numbers	Product Code Description	Staple Line Length	Subject Device Reloads	Predicate Device Model Numbers	Predicate K Number
GTX30	ETHICON™ Linear 30mm Stapler	30mm	GTXR30B GTXR30G	TX30B; TX30G Compatible Reloads: XR30B (Blue) XR30G (Green)	K020779
GTX60	ETHICON™ Linear 60mm Stapler	60mm	GLCR60B GLCR60G	TX60B; TX60G Compatible Reloads: XR60B (Blue) XR60G (Green)	K020779
GTX90	ETHICON™ Linear 90mm Stapler	90mm	GLCR90B GLCR90G	There is no 90mm Predicate device, therefore, 30mm and 60mm devices used to show substantial equivalence.	K020779

Reload codes and corresponding Reload color

30 mm Reloads Codes	60 mm Reload Codes	90 mm Reloads Codes	Corresponding Reload Color
GTXR30B	GTXR60B	GTXR90B	Blue
GTXR30G	GTXR60G	GTXR90G	Green

IV. DEVICE DESCRIPTION

The ETHICON™ Linear Stapler delivers two staggered rows of titanium staples in order to approximate internal tissues. The Subject device is sterile, single patient, disposable device used in conjunction with reloadable ETHICON™ Linear Stapler 3D Reloads to staple tissue in one firing stroke. The Subject device is a next generation Linear Stapler to be used in open procedures requiring a surgical stapler. The Subject device incorporates proven Gripping Surface Technology (GST) Reload Technology, leveraged from Ethicon Endocutters, along with a 3-D staples developed for other Ethicon Endocutters and open mechanical devices.

The ETHICON™ Linear Stapler 30 mm, 60 mm and 90 mm Staplers are sterile, single- patient-use instruments that staple tissue. There are two staggered rows of staples, on either side of the staple line. This device may be used on the general population for routine wound closure via stapling.
The 30 mm reload creates a 30 mm staple line. The 60 mm reload creates a 60 mm staple line. The 90 mm reload creates a 90 mm staple line.

The 90mm device and compatible reloads have also been developed. The 90mm device can be used by surgeons who prefer to use a 90mm device when transecting wider tissue such as completing the closure of a side-to-side anastomosis or when performing a sleeve gastrectomy. The Predicate device does not currently offer a 90mm size but the principles of operation are the same as the 30mm and 60mm devices. Design verification testing demonstrates that the 90mm device and compatible reloads do not raise new types of safety or effectiveness questions.

The instruments are shipped without a reload and must be loaded prior to use. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. The instrument may be loaded eight times for a maximum of eight firings per instrument during a single procedure. There are blue and green reload options for each device size.

The instruments' lock-out feature is designed to prevent a used or improperly installed reload from being refired or an instrument from being fired without a reload.

V. INDICATIONS FOR USE

The ETHICON™ Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.

Indication for Use Comparison Table

Subject Device	Predicate Device	Difference
The ECHELON LINEAR™ Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.	The Proximate® Reloadable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.	The indications are the same.

VI. TECHNOLOGICAL COMPARISON

Subject and Predicate Device and Reload Comparison Table

Characteristics	Subject Device	Predicate Device
General Information		
Stapler Code	GTX30, GTX60, GTX90	TX30B, TX30G TX60B, TX60G
Compatible Reloads	GTXR30B, GTXR60B, GTXR90B Green: GTXR30G, GTXR60G, GTXR90G	XR30B, XR60B Green: XR30G, XR60G
How it is supplied	Provided sterile, single patient use	Same
Packaged	PETG Tray	Same
Sterilization Method	Gamma	Same
Sterility Assurance Level	SAL 10-6	Same
Design Features		
Operation of stapling and transection of tissue	The device operates by driving staples into a staple forming anvil to staple tissue	Same
Cartridge Reload surface	GST Reload Technology for cartridge deck surface	Flat cartridge deck surface
Number of staple rows	2 Staggered Rows	Same
Staple material	Titanium Alloy -Ti3Al-2.5V Wire	Titanium Alloy (Ti-6Al-4V)
Formed staple geometry	3D final staple form	2 D shaped staple form
Principle of Operation		
Environment of Use	Surgical facility	Same
Intended population	General	Same
Energy Type	Manual	Same
Maximum number of Firings per device	8 Firings	Same

Regulatory History

The Regulatory History of the predicate device ETHICON™ Linear Stapler is provided in the Table below to help clarify the submissions associated with the predicate.

Regulatory History of the Predicate Device

Submission Number	Description	Clearance Date
K020779	PROXIMATE® TX Reloadable Linear Stapler	05-JUN-2002

VII. 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 Performance 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
  - Force to Fire
  - Jaw Aperture
  - No Spent Reload/Lockout
  - Human Factor Report/Usability Testing
- Product Characterization
  - Staple line Strength Test

Animal Testing: In-vivo testing evaluations included.

- Acute Hemostasis evaluation study
- Tissue Healing response, Survival Study

All animal studies passed the criteria for success.

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

Bio-compatibility: studies was performed based on ISO 10993-1 and confirmed that the proposed device is biocompatible for the intended patient contact profile.
All biocompatibility studies passed the criteria for success.

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

VII. CONCLUSIONS

The conclusions of the testing criteria demonstrate that the Subject device; ETHICON™ Linear Stapler performs substantially equivalent to the Predicate device and does not raise new questions of safety and effectiveness.