January 09, 2026

Ethicon Endo-Surgery LLC
Roberta Franca
Regulatory Affairs, Senior Program Lead
475 Calle C , PR UNITED STATES
Guaynabo, PR 00696

Re: K252906
Trade/Device Name: ECHELON ENDOPATH Staple Line Reinforcement (ECH60R)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXC
Dated: September 11, 2025
Received: September 12, 2025

Dear Roberta Franca:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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

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.

510(k) Number *(if known)*
K252906

Device Name
ECHELON ENDOPATH™ Staple Line Reinforcement (ECH60R)

Indications for Use *(Describe)*
ECHELON ENDOPATH™ Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. ECHELON ENDOPATH™ Staple Line Reinforcement can be used for reinforcement of staple lines during lung resection and bariatric surgical procedures. The device can also be used for reinforcement of staple lines during gastric, small bowel, and colorectal procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

(K252906)

I. SUBMITTER

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

Contact: Roberta Cabral França
Regulatory Affairs Senior Program Lead
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Date Prepared: December 12, 2025

II. SUBJECT DEVICES

Trade Name: ECHELON ENDOPATH™ Staple Line Reinforcement
Product Code: ECH60R
Classification Name: Mesh, Surgical, absorbable, staple line reinforcement
Classification Regulation: 21 CFR 878.3300
Device Class: II
Product Code: OXC

III. Predicate DEVICES

Predicate Device 510(k) Number	Predicate Device Name	Model
K221343	ECHELON ENDOPATH Staple Line Reinforcement	ECH60R

Reference Device

Reference Device 510(k) Number	Reference Device Name	Model
K190937	ECHELON ENDOPATH Staple Line Reinforcement	ECH60R

IV. Device Description

Echelon Endopath™ Staple Line Reinforcement is a staple line reinforcement, also known as a buttress, for use in the surgical environment for the purpose of reinforcing a staple line.

This submission is to increase the maximum sterilization dose from 25-30 kGy to 25-40 kGy and device Shelf-Life from 2 years to 3 years. There are no changes to the device itself associated with this submission.

Echelon Endopath™ Staple Line Reinforcement is to be used with surgical stapling devices. Surgical stapling devices place staggered rows of staples with a reinforcement material and simultaneously divide the tissue and the reinforcement material between the stapled rows.

The Subject Device is an absorbable staple line reinforcement material which is secured to both the stapler anvil and reload with a synthetic attachment material. The product consists of an applicator which includes the implantable device, one for each of the upper and lower stapler jaws. The implantable material consists of 3 materials: the Vicryl material, the Polydioxanone film and the attachment adhesive material.

Echelon Endopath™ Staple Line Reinforcement is an implanted material which works as an adjunct to surgical staples after transection, to provide support to soft tissue during the healing process. There are no modifications to the design of the Predicate device; and the materials of the Subject Device and Predicate Device are the same. Each unit is packaged sterile in separate pouch.

V. Subject Device Indications for Use

There are no changes to the intended use: "ECHELON ENDOPATH™ Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. ECHELON ENDOPATH™ Staple Line Reinforcement can be used for reinforcement of staple lines during lung resection and bariatric surgical procedures. The device can also be used for reinforcement of staple lines during gastric, small bowel and colorectal procedures".

VI. Technological Comparison

Characteristic	Predicate Device (K221343)	Subject Device (K252906)
Product Descriptor Code	ECH60R	Same
How Supplied	Sterile, single patient use	Same
Biocompatibility of materials	Yes, guided by ISO 10993-1	Same
Packaging	Foil	Same
Sterilization method	E-Beam Irradiation	Same
Sterility Assurance Level	SAL 10^{-6}	Same
Implanted Material Composition	Polyglactin 910 (Vicryl™ Knit) laminated with Polydioxanone – (PDO Film) Poloxamer blend (BAM) No pigments or dyes	Same
Implant Absorption Process	Hydrolysis	Same
Implant Physical Dimensions	Length: 65.367 ± 0.30 mm Width: 10.4 ± 0.30 mm	Same
Device Applicator Component	Hand-held polycarbonate applicator	Same
Absorption Rate	120 days	Same
Storage Conditions	Room Temperature, cool dry place not to exceed 30º C	Same
Key Differences		

Characteristic	Predicate Device (K221343)	Subject Device (K252906)
Sterilization Dose (E-Beam Irradiation)	25-30 kGy	25-40 kGy
Shelf Life	2 years	3 years

VII. Non-Clinical and/or Clinical Tests

The non-clinical tests that have been submitted include:

- Device Performance Tests:
- Staple Pull Through
- Buttress Alignment in Applicator
- Reload Shear Force (device applied)
- Release force
- Packaging Verification
- Seal Strength
- Oxygen Content
- Biocompatibility
- Chemical Characterization
- Cytotoxicity
- Material Stability
- Acute Systemic Toxicity
- Sensitization
- Intracutaneous Irritation
- Pyrogenicity
- Genotoxicity
- Systemic Toxicity - Subcutaneous Implantation – 4 week
- Sub-chronic toxicity - 13 week
- Subcutaneous implantation endpoint related to device degradation: the Gastric Intended Use GLP Canine study conducted at 40 kGy, with timepoints at 10, 28, and 120 days is included in this submission. This study aligns with the complete degradation profile of the absorbable device with the increased sterilization dose. Also included in the submission is a retrospective comparison of implant studies for predicate and subject device at original and increased dose, as agreed upon with the FDA during the Pre-Submission Q231522.

Clinical Tests

This premarket submission did not rely on the assessment of clinical performance data to demonstrate device performance and equivalence.

VIII. Predetermined Change Control Plan

The predetermined change control plan (PCCP) for the device specifies anticipated modifications to the device packaging design per table below.

Planned Modification	Test Methods and Validation Activities	Communication to Users, as needed
Change in the device packaging that involves transitioning from existing flexible foil packaging to a new pre-formed high barrier flexible foil laminate tray design with moisture-absorbing and oxygen-scavenging materials due to material obsolescence.	Packaging design verification, package functionality and stability testing per Modification Protocol will confirm that packaging will continue to protect device from transit forces and maintain sterility.	Labeling will be updated to provide users with current device packaging illustrations as applicable.

Implementation of the predetermined change control plan does not affect the substantial equivalence to the predicate.

IX. Conclusion

In conclusion, based upon the Intended Use, Indications for Use, product information, performance testing, proposed modifications outlined in the PCCP, and standards compliance provided in this premarket notification, the Subject device (K252906) has been shown to be substantially equivalent to the Predicate devices and does not raise any new questions of safety and effectiveness.