September 16, 2022

Ethicon Endo-Surgery LLC
Rubina Dosani
Manager, Regulatory Affairs
475 Calle C
Guaynabo, PR 00696

Re: K221343
Trade/Device Name: ECHELON ENDOPATH Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXC
Dated: August 17, 2022
Received: August 18, 2022

Dear Rubina Dosani:

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 Deborah Fellhauer, RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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.

510(k) Number *(if known)*
K221343

Device Name
Echelon Endopath Staple Line Reinforcement

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.

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510(k) Summary

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

Contact
Rubina Dosani,
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
Telephone: 513.337. 3566
Email: rdosani@its.jnj.com

Date Prepared:	September 15, 2022
Trade Name:	Echelon Endopath Staple Line Reinforcement
Common Name:	Staple Line Reinforcement Material
Classification Name:	Surgical mesh
Classification:	21CFR 878.3300
Product Code:	OXC
Device Class:	Class II
Panel:	79, General and Plastic Surgery
Predicate Device	Echelon Endopath Staple Line Reinforcement cleared under K190937
Reference Device	Intuitive Surgical SureForm™ 60 and SureForm™ 60 Reloads cleared under K173721

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.

The Subject Device of this 510(k) is the same as the Predicate Device with a modification to the labeling to include the addition of the Intuitive Surgical SureForm™ 60 mm Blue, Green and Black Reloads and SureForm™ 60 mm Stapler 510(k) Cleared K173721 as compatible devices. The Predicate Device is compatible with the Echelon Flex™ 60 mm Powered Plus Articulating Endoscopic Linear Cutters with Echelon Endopath 60 mm Endoscopic Linear Cutter Reloads with Gripping Surface Technology, (510k cleared K202665, K183435). There are no design or manufacturing changes associated with this submission.

The Subject Device 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 predicate device; and the materials of the Subject Device and Predicate Device are the same. Each unit is packaged sterile in separate pouch.

Indications for 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.

Summary of Similarities and Differences in Technological Characteristics

There are no technological differences between the Subject and the Predicate Device. There are no changes to the intended use, design, materials, sterilization, manufacturing or packaging between the Subject Device and Predicate Device.

Performance Data

Bench testing was performed, as appropriate for the required endpoint to demonstrate that the performance of the Subject Device with the proposed compatible Stapler and reloads (Intuitive Surgical SureForm™ 60 mm Stapler and SureForm™ 60 mm Blue. Green and Black Reloads) is substantially equivalent to the performance of the Predicate Device with the approved compatible Stapler and Reloads (Echelon Flex 60 mm Powered Plus and any Echelon Endopath 60 mm Reloads with GST Technology). Testing performed to support the change is as follows:

- Device Compatibility with Stapler and Reloads
    - Staple Form Quality
    - Staple Line Integrity
- Manipulation of device on tissue,
    - Buttress security on Surgical Stapler and Reload
    - Release Force
    - Shear Force
- Usability Testing

All bench studies passed the criteria for success.

Animal Testing

No changes were made to device indications of use, function, technology or materials. Therefore, no new animal studies were needed to demonstrate substantial equivalence of the subject to the predicate device.

Conclusion

Echelon Endopath Staple Line Reinforcement maintains the same intended use, indications for use, materials, and principle of operation as its predicate device. The addition of a new compatible Stapler and reloads does not impact these product characteristics. Testing of the product for compatibility was completed using the same or similar test methods as the Predicate device.

The conclusions of the testing demonstrate that Echelon Endopath Staple Line Reinforcement Subject Device is substantially equivalent to the legally marketed Echelon Endopath Staple Line Reinforcement Predicate Device. No new issues of safety and effectiveness have been identified.