October 14, 2019

Ethicon Endo-Surgery LLC
Emily Nesbitt
Associate Director, Regulatory Affairs
4545 Creek Rd
Cincinnati, Ohio 45242

Re: K190937
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: September 10, 2019
Received: September 13, 2019

Dear Emily Nesbitt:

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 Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190937

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
Emily Nesbitt (née Kruetzkamp),
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
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Email: enesbitt@its.jnj.com

Date Prepared:	April 9, 2019
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:	General and Plastic Surgery
Predicate Device	Gore Seamguard Bioabsorbable Staple Line Reinforcement cleared under K032865
Reference Device	Vicryl (Polyglactin 910) Mesh, K810428

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 is to be used Echelon Endopath GST 60 mm reloads in conjunction with the Echelon family of 60 mm endoscopic linear cutters. The Echelon 60 mm Stapler in conjunction with the Echelon Endopath GST60 mm reload places staggered rows of titanium 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 the stapler anvil and reload with a synthetic attachment material. The Subject Device contains an applicator and the implantable device which consists of 3 materials: the Vicryl material, the Polydioxanone film and the attachment 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.

The Echelon Endopath Staple Line Reinforcement Subject Device and Predicate Device have identical intended use: to support staple line reinforcent in soft tissue. The Subject Device has a

smaller list of anatomical sites than the Predicate Device, and the Subject Device is a subset of the Predicate Indications.

The Echelon Endopath Staple Line Reinforcement Subject Device and Predicate Device are both synthetic, absorbable staple line reinforcement materials to be applied to staplers to provide support to the staple line during the tissue healing process. The Subject Device is to be applied to the Ethicon Echelon Flex Powered Plus Stapler. Both materials degrade via hydrolysis and have been evaluated for biocompatibility in alignment with ISO 10993-1 and are deemed biocompatible.

Echelon Endopath Staple Line Reinforcement is composed of undyed multifilament fibers identical to those used in Vicryl surgical sutures. The polyglactin 910 implant is knitted by a process which interlocks each fiber juncture to prevent unraveling. The implanted material consists of a Vicryl layer laminated with a PDO film on each side, and a Buttress Attachment Material which is a synthetic material applied to the top outer surface of each implant. The staple line reinforcement is used as a buttress to provide support during the healing process. Both Subject and Predicate materials are hydrolyzed by body fluids and absorbed after serving the intended function. The subject Device absorption is essentially complete at 120 days.

The primary difference between the Subject and Predicate Devices is the feature for loading and delivery of the device to the implantation site. A thin layer of bioabsorbable adhesive is coated onto one surface of the implantable device and is composed of a synthetic polymer/poloxamer blend to attach the Subject Device to the stapler. Whereas the Predicate Device utilized a sleeve construction and suture pullcord to secure the reinforcement material on the stapler.

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

Staple line reinforcement is the technological principle for both the Subject Endopath Echelon Staple Line Reinforcement and the Predicate Gore® Seamguard® Reinforcement device. It is based on the use of applying an absorbable material, also known as a buttress, as a reinforcement to the transected surgical staple line in soft tissue. At a high level, the Subject and Predicate Devices are based on the following same technological elements:

- Staple line reinforcement device is applied to a surgical stapler
- Staple line reinforcement and stapler are positioned on the desired anatomical area to be transected
- Stapler is fired, knife proceeds to transect tissue, and staples with buttress are applied to the tissue
- Absorbable implant reinforces tissue and helps to secure the staple line

The Endopath Echelon Staple Line Reinforcement differs from Predicate Gore® Seamguard® Reinforcement device in the Steps for Use to load the buttress device onto the surgical stapler. The Subject Device uses an attachment material to permit temporary attachment to the surgical stapler.

Both devices are sterile, single use, absorbable implants that absorb over time. The Subject Device absorbs over approximately 120 days, the Predicate Device absorbs over approximately 180 days.

Performance Data

Performance tests were performed ex-vivo and in-vivo, as appropriate for the required endpoint, to demonstrate the ECHELON ENDOPATH Staple Line Reinforcement is substantially equivalent to the Predicate Device.

Ex-vivo evaluations include design verification testing of the ECHELON ENDOPATH Staple Line Reinforcement, including:

- Device Implant Characterization
    - Thickness
    - Porosity
    - Density
    - Tensile
    - Stiffness
    - Tear Resistance
    - Burst strength
    - Staple pull out strength
- Device Compatibly with Staplers and Reloads
    - Force to Close
    - Staple Height
    - Staple Form Quality
    - Staple Line Integrity
    - Release of stapled reinforcement material from Endocutter
- Manipulation of device on tissue, buttress security on surgical stapler

Preclinical in-vivo evaluations include studies with animal models which support the intended use of the ECHELON ENDOPATH Staple Line Reinforcement, demonstrating performance in the indicated gastric, thoracic, small bowel, and colon/colorectal procedures. The surgical functionality of the Subject Device, such as device attachment to the surgical stapler and usability, was demonstrated in animal studies. In-vivo testing evaluations include:

- Hemostasis, bleeding at the staple line
- Tissue healing response, survival studies: Gastric, thoracic tissue absorption, Perpendicular firings, L-shaped firings, Sequential Firings

- Usability of the Subject Device
- Abrasion evaluation on tissue, survival study

Animal tests were performed to verify that the Subject Device meets the definition of substantial equivalence to the Predicate Device.

Stability studies were conducted, and the shelf life of the device was demonstrated. Biocompatibility evaluation was performed and confirmed that the proposed device is biocompatible for the intended patient contact profile. Subject Device is a medical device implant for use on tissue with long-term (>30 days) patient exposure. The patient-contacting materials used in the Subject Device are categorized as Long-term patient contacting materials.

Consensus Standards
All components of the Echelon Endopath Staple Line Reinforcement are comprised of materials which are in accordance with ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

Clinical

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

Conclusion

The conclusions of the testing criteria demonstrate that ECHELON ENDOPATH Staple Line Reinforcement is as safe and effective and performs as well as the legally marketed Predicate Device, Gore Seamguard K032865 in terms of intended use, design, materials, biocompatibility, sterility, and performance.