February 6, 2019

Ethicon Endo-Surgery, LLC
% Brian Ruble
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc
4545 Creek Road
Cincinnati, Ohio 45245

Re: K183435
Trade/Device Name: Echelon Endoscopic Linear Cutter Reloads, White, Blue, Gold, Green and Black
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 7, 2018
Received: December 11, 2018

Dear Mr. Ruble:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

Digitally signed by David Krause -S
Date: 2019.02.06 12:56:59 -05'00'

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K183435

Device Name
The ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX™ families of Endoscopic Linear Cutters and Reloads

Indications for Use *(Describe)*
The ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX™ families of Endoscopic Linear Cutters and Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

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

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

Contact Brian Ruble
Associate Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1593
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Date Prepared: December 07, 2018
Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Staple, implantable (21 CFR 878.4750)
Regulatory Class: Class II
Product Code: GDW

Subject Device Trade Name

Echelon Endoscopic Linear Cutter Reload, White (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Blue (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Gold (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Green (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Black (+ Gripping Surface Technology)

Predicate Devices Trade Name (K140560)

Echelon Endoscopic Linear Cutter Reload, White (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Blue (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Gold (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Green (+ Gripping Surface Technology)
Echelon Endoscopic Linear Cutter Reload, Black (+ Gripping Surface Technology)

Device Description

The ENDOPATH ECHELON™ and ECHELON FLEX™ families of endoscopic linear cutters are sterile, single patient use instruments that simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line. The ECHELON 60 instruments have a staple line that is approximately 60 mm long and a cut line that is approximately 57 mm long. The shaft can rotate freely in both directions and an articulation mechanism on articulating instruments enables bending the distal portion of the shaft to facilitate lateral access of the operative site.

The ECHELON ENDOPATH™ Echelon Endoscopic Linear Cutter Reloads come in five colors corresponding to different closed staple heights, with the intention of being used in different tissue thickness.

The instruments are packaged with a primary lithium battery pack that must be installed prior to use.

The instruments are packaged 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 instruments' lock-out feature is designed to prevent a used or improperly installed reload from being re-fired or an instrument from being used in different tissue thickness.

The ECHELON ENDOPATH™ Echelon Endoscopic Linear Cutter Reloads (+ Gripping Surface Technology) are designed for use with the Echelon Endoscopic Linear Cutter devices (Echelon, Echelon Flex, Echelon Flex Powered and Echelon Flex Powered Plus) in a 60mm configuration.

Indications for Use
The ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX™ families of Endoscopic Linear Cutters and Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Technological Characteristics
The design and performance of the subject device is based on the currently marketed Echelon Endoscopic Linear Cutter Reloads. The changes described in the submission do not affect the intended use of the devices or alter fundamental scientific technology of the device. Magnetic Resonance studies are not required because the dimensional changes in the cartridge sub assembly will not impact the shape and form of the staples. Surgical Stapling is the technological principle for both the subjects and predicate devices. It is based on the use of endoscopic instrumentation for transection, resection and/or creation of anastomoses.

Performance Data
Bench testing was performed to demonstrate that the changes introduced in the updated devices support substantial equivalence to the predicate device.

Labelling
Update to IFU, Tyveks and Cartons to bring them up to date with current global labelling requirements.

Sterilization
The subject devices will be sterilized by Cobalt 60 irradiation. The device will be validated to a minimum sterilization (radiation) dose of 25 kGy to achieve a 10^{-6} sterility assurance level (SAL).
The sterilization process will be validated, and the sterilization dose will be established per the requirements of the following FDA recognized standards:
ISO 11137-1:2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (FDA Recognition Number 14-328).

ISO 11137-2:2012 – Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (FDA Recognition Number 14-364).
The subject devices are intended for single patient use and are not intended to be reused or re-sterilized.

ISO11737-1:2006, Sterilization of health care product-Microbiological methods- Part 1: Determination of the population of microorganisms on product.

ISO11737-2:2009, Sterilization of Medical Devices-Part 2: Tests of sterility performed in the validation of a sterilization process.

Biocompatibility Testing
Biocompatibility testing was not required for this submission as no new materials were introduced on this device. All materials are already cleared under the predicate device submission (K140560).

Electrical Safety and Electromagnetic Compatibility
Electrical Safety and Electromagnetic Compatibility section does not apply because the Echelon Endoscopic Linear Cutter Reloads (+ Gripping Surface Technology) do not contain any electronics.

Bench Testing
Force to Close, Staple Form Quality, Formed Staple Height and Staple Line Integrity were evaluated for Echelon Endoscopic Linear Cutter Reloads (+ Gripping Surface Technology) to support substantial equivalence to the predicate device.

Clinical Testing
Clinical Testing section is not applicable. No clinical data was collected to demonstrate equivalency.

Conclusion

Four outputs from the staple-line testing were evaluated for equality with the primary goal of improving the cartridge pan retention at the proximal end of the reload to predicates. In all cases, the subject reloads demonstrated equivalent performance relative to the predicates. The overall results from the bench testing are therefore acceptable since the subject reloads demonstrated substantial equivalency to the predicate device.