DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 5, 2017

Ethicon Endo-surgery, LLC
% Ms. Asifa Vonhof
Ethicon Endo Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K163454
Trade/Device Name: Echelon Flex 45mm Powered Plus Articulating Endoscopic Linear Cutters, Echelon Endopath Endoscopic Linear Cutter Reloads, 45mm
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 7, 2016
Received: December 9, 2016

Dear Ms. Vonhof:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K163454

Device Name

The ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads

Indications for Use *(Describe)*

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

I. SUBMITTER

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

Phone: 513-337-3118
Fax: 513-337-1122

Contact Person: Ms. Asifa Vonhof, MS, RAC
Date Prepared: January 5, 2017

II. DEVICE

- ECHELON FLEX™ 45mm Powered Plus Articulating Endoscopic Linear Cutters
- ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads, 45mm (+ Gripping Surface Technology)

Common or Usual Name:	Surgical Stapler with Implantable Staples
Classification Name:	Staple, implantable (21 CFR 878.4750)
Regulatory Class:	II
Product Code:	GDW

III. PREDICATE DEVICES

- ECHELON FLEX™ 60mm Powered Plus Articulating Endoscopic Linear Cutters (K140560, K160521)
- ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads, 60mm (+ Gripping Surface Technology) (K140560)

Reference device
Echelon Endoscopic Linear Cutter Reload, Black (K131663, K112056)

IV. DEVICE DESCRIPTION

The ECHELON, ECHELON ENDOPATH and ECHELON FLEX families of endoscopic linear cutters and reloads 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 FLEX™ 45 mm Powered Plus instruments have a staple line that is approximately 45 mm long and a cut line that is approximately 42 mm long. The shaft can rotate freely in both directions and an articulation mechanism enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

The instruments are packaged with a primary lithium battery pack that must be installed prior to use. There are specific requirements for disposing of the battery pack. Refer to the Battery Pack Disposal section.

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 refired or an instrument from being fired without a reload.

The ECHELON ENDOPATH™ Echelon Endoscopic Linear Cutter Reloads are sterile, single patient use devices. They come in five colors corresponding to different closed staple heights, with the intention of being used in different tissue thicknesses.

They are loaded into a Linear Cutter and deliver staples into the tissue when the instrument is fired. There are 70 staples in the 45mm length reload.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICES

Surgical stapling is the technological principle for both the subject and predicate device. It is based on the use of endoscopic instrumentation for transection, resection, and/or creation of anastomoses.

The subject and predicate staplers have the following identical features:
- intended use
- indications
- contraindications
- technological characteristics
- design
- materials
- operational principles

The following differences exist between the subject and predicate staplers:
- Anvil length (45mm vs 60mm)
- Cut-line length (42mm vs 57mm)

The subject and predicate reloads have the following identical features:
- intended use
- indications
- contraindications
- technological characteristics
- materials
- operational principles
- MR compatibility

The following differences exist between the subject and predicate reloads (marketed):
- Length of reload (45mm vs 60mm)
- Number of staples (70 vs 88, to accommodate 45mm reload length)
- Sled component of white 45mm reload differs in design from the white 60mm reload
- Wire diameter of the 45mm blue reload differs from the wire diameter of the 60mm blue reload

VII. PERFORMANCE DATA

Signed Declarations of Conformity with Design Controls for verification and validation activities and the manufacturing facility are provided.

Risk analyses for each device modification are provided, according to *EN ISO 14971:2012, Medical Devices - Application of Risk Management to Medical Devices*.

During verification and validation testing, all acceptance criteria were met.

Non-Clinical Tests used to demonstrate substantial equivalence:

- Formed Staple Height
- Staple Form Quality
- Staple Line Integrity
- Staple Line Reinforcement Compatibility
- System Reliability.

VIII. CONCLUSIONS

The risk profile of the device has not changed as a result of the described changes; furthermore, the performance of the modified device is consistent with the predicate device and does not raise any new questions of safety and effectiveness.