DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 22, 2016

Ethicon Endo-surgery, LLC
% Mr. Kweku Biney
Regulatory Affairs Specialist
Ethicon Endo-surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K160521
Trade/Device Name: Echelon Flex 60 Powered Plus Compact Articulating Endoscopic Linear Cutter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 24, 2016
Received: February 25, 2016

Dear Mr. Biney:

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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160521

Device Name

ECHELON FLEX Powered Plus Compact Articulating Endoscopic Linear Cutter

Indications for Use *(Describe)*

The ENDOPATH ECHELON™ 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.

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510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Contact Kweku Biney
Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
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Date Prepared: February 24th, 2016

Device Name

Trade Name: Echelon Flex Powered Plus Compact Articulating Endoscopic Linear Cutter

Common or Usual Name: Cutter/Stapler

Model Number: PCEE60A

Classification Name:

Staple, Implantable; Stapler, Surgical (GDW 21 CFR 878.4750)

Predicate Device

Echelon Flex Powered Plus Articulating Endoscopic Linear Cutter (Cleared under K140560)

Device Description

The ECHELON FLEX Powered Plus Compact Articulating Endoscopic Linear Cutter is a 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 60 Powered Plus 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 enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

Indications for Use

The ECHELON families of endoscopic linear cutters 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 Echelon Flex Powered Plus Compact Articulating Endoscopic Linear Cutter *(subject device)* is a sterile, single patient use instrument. The instrument utilizes an insulated tubular shaft, an ergonomic handle with an integrated motor, and battery power to simultaneously transect (cut) and staple tissue. The instrument also features an articulation system that can adjust the end effector in increments of 15° to a maximum of 45°. As compared to Echelon Flex Powered Plus Articulating Endoscopic Linear cutter (predicate), the shaft of the subject device is shorter than that of the predicate, in addition, incremental changes that have been made include a manual override change and articulation connector change.

The modification described in this submission does not affect the intended use of the device or alter the fundamental scientific technology of the device, summary information from the design control process serve as the basis for this submission.

Performance Data

Ex-vivo tests (bench) were performed to ensure that the devices performed as intended and met design specifications. Device performance was assessed against the design requirements. Risk analyses and design verification testing was also conducted for the changes described in this submission to ensure that the performance of the device was not affected by the device modifications. The results of all verification supports the conclusion that the performance of the device has not been affected by the changes made to the device. The verification testing that was done include form staple height, stable line integrity and staple form quality for the shaft dimension change; force to fire, reliability testing and angle of articulation testing for the articulation connector change; and ergonomic device weight test, bailout system tests, and reliability test for the manual override change.

Conclusion

The Echelon Flex™ Powered Plus Compact Articulating Endoscopic Linear cutter is substantially equivalent to the legally marketed predicate device based upon intended use, technological characteristics, and performance testing.