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

November 24, 2014

Ethicon Endo-Surgery, LLC.
% Ms. Linda Hill
Ethicon Endo-Surgery Incorporated
4545 Creek Road
Cincinnati Ohio 45242

Re: K141952
Trade/Device Name: Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip, and Endopath Echelon™ Vascular White Reloads for Advanced Placement Tip
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 25, 2014
Received: October 27, 2014

Dear Ms. Hill:

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" (21CFR 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)*
To be assigned K141952

Device Name
Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip, and Endopath Echelon™ Vascular White Reloads for Advanced Placement Tip

Indications for Use *(Describe)*
The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and its reloads are intended for transection and resection of tissue and vasculature. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical 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)

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

Company Ethicon Endo-Surgery, LLC
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Date Prepared July 17, 2014

Device Name
Trade Name: Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip, and ENDOPATH Echelon™ Vascular White Reloads for Advanced Placement Tip

Common or Usual Name: Surgical Stapler with Implantable Staples

Classification Name: Staple, Implantable

Predicate Devices
Echelon Flex Powered Articulating Endoscopic Linear Cutters, 45mm, 60mm (K110385, K081146)
ENDOPATH ETS Flex Articulating Linear Cutter, 35mm (K111111, K070887, K020779)
Echelon Endoscopic Linear Cutter Reload, White (K121600, K081146, K070887)
ENDOPATH ETS Endoscopic Reload, White (K111111, K 070887, K020779)

Device Description
The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and ENDOPATH Echelon Vascular White Reload for Advanced Placement Tip (35mm, 4 Row) reloads are sterile, single patient use devices that simultaneously cut and staple tissue. There are four staggered rows of staples, two on either side of the cut line. The Echelon Flex Powered Vascular Stapler with Advanced Placement Tip and reloads have a staple line that is approximately 35 mm long and a cut line that is approximately 30 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 access to the operative site.

The instrument is packaged with a primary lithium battery pack that must be installed prior to use. The instrument is 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, transporting, and installing the reload. The instrument's lockout feature is designed to prevent a used or improperly installed reload from being refired or an instrument from being fired without a reload.

Indications for Use

The Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip and its reloads are intended for transection and resection of tissue and vasculature. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures.

Technological Characteristics

The subject Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip instrument is similar to the predicate Echelon Flex Powered Articulating Endoscopic Linear Cutters with respect to the powered handle, and closure and firing design for minimal tip movement. The subject instrument is similar to the predicate ENDOPATH ETS Flex 35mm Articulating Linear Cutter and Reloads with respect to the active articulation feature and to the tissue compression aspects of the end effector, with similar jaw length and staple line length. As compared with the predicate devices, the subject Echelon Flex™ Powered Vascular Stapler with Advanced Placement Tip instrument incorporates several design enhancements – including a narrower diameter shaft, narrower end effector tip, curved anvil tip, introducer-like cartridge body tip, and active articulation with higher maximum articulation angles – which facilitate access in surgical procedures with smaller surgical spaces or difficult-to-reach vessels.

The subject reload, the ENDOPATH Echelon™ Vascular White Reloads for Advanced Placement Tip, is similar to the predicate ENDOPATH ETS Endoscopic Reload, White, 35mm with regard to staple material (titanium alloy), reload color (white), intended tissue type (thin/vascular), and closed staple height (1.0mm). The principal difference between the subject reload and predicate reloads is that the subject reload, which features a narrower design, delivers 2 sides of double staggered staple lines, rather than 2 sides of triple staggered staple lines as in the predicate device.

Performance Data

Testing conducted to demonstrate that the subject device will perform equivalently to the identified predicate devices for the intended use included: bench testing for force-to-close evaluation; staple height, staple form, and staple line integrity evaluation; animal testing for hemostasis evaluation (in acute and survival models); electrical safety and electromagnetic compatibility testing; MR compatibility testing; and aggregate device biocompatibility testing for patient contacting materials.