510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Guaynabo, PR 00969

APR 2 2 2014

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Date Prepared April 15, 2014

Device Name
Trade Name:
Echelon Flex Powered Plus Articulating Endoscopic Linear Cutter
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)

Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Staple, Implantable

Predicate Devices
Echelon Flex Powered Articulating Endoscopic Linear Cutters (K130653, K110385) Echelon Endoscopic Linear Cutter Reload, White (K121600, K070887, K051002)
Echelon Endoscopic Linear Cutter Reload, Blue (K070887, K051002)
Echelon Endoscopic Linear Cutter Reload, Gold (K070887, K051002)
Echelon Endoscopic Linear Cutter Reload, Green (K070887, K051002)
Echelon Endoscopic Linear Cutter Reload, Black (K131663 K112056)

Device Description

The Echelon Flex Powered Plus Articulating Endoscopic Linear Cutters are sterile, single patient use instruments that simultaneously cut and staple tissue through a battery powered firing system. The instruments deliver six staggered rows of staples, three on either side of the cut line. The instruments are available in two shaft lengths: regular and long. The shaft can rotate freely in both directions and incorporates an articulation mechanism, which enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

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

Technological Characteristics
The design and performance of the subject devices is based on the currently marketed Echelon Flex Powered platform of Linear Cutters and reloads. The changes described in this submission do not affect the intended use of the devices or alter fundamental scientific technology of the devices. Many of the new features added to the reloads were introduced in prior reload submissions (K112056, K121600). MR compatibility data has been derived from the testing performed for the currently marketed Echelon Black reload. The data for the Black reload represents the worst case scenario, due to its larger staple design and greater mass.

Performance Data
Performance testing conducted to determine the new devices were substantially equivalent to the predicates, included; Biocompatibility (per ISO 10993-1:2009), Electrical Safety (per AAMI / ANSI ES 60601-1:2005/(R) 2012), Electromagnetic Compatibility (per IEC 60601-1-2 edition 3:2007-03) and Bench Testing (Force to Close, Staple Form Quality, Formed Staple Height, Staple Line Integrity and Compatibility with buttress material).

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

April 22, 2014

Ethicon Endo-Surgery, LLC
Asifa Vonhof
Regulatory Affairs Associate II
4545 Creek Road
Cincinnati, Ohio 45242

Re: K140560
Trade/Device Name: The ENDOPATH ECHELON™ and ECHELON FLEX™ families of endoscopic linear cutters and reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 4, 2014
Received: March 5, 2014

Dear Mr./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 Small Manufacturers, International and Consumer Assistance 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.
Acting 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)*
K140560

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

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)

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)*

Peter L. Hudson
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