510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Guaynabo, PR 00969

Contact Christina Canter, RAC
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OCT 18 2013

Date Prepared June 6, 2013

Device Name
Trade Name: Echelon Endoscopic Linear Cutter Reload, Black
Common or Usual Name: Endoscopic and Accessory
Classification Name: Staple, Implantable

Predicate Devices
Echelon Endoscopic Linear Cutter Reload, Black (cleared under K112056)

Device Description
The Echelon Endoscopic Linear Cutter Reload, Black, is a thick tissue reload for use with the Echelon Endoscopic Linear Cutter devices (Echelon, Echelon Flex, Echelon Powered Flex) in a 60mm configuration. It is part of the current Echelon reload family and provides a closed staple height of 2.3 mm for use in thick tissue such as gastric, lung, and solid organ.

The Echelon Endoscopic Linear Cutter Reload, Black is loaded into an Echelon Endoscopic Linear Cutter and delivers staples into the tissue when the instrument is fired.

Indications for Use
The ECHELON and ECHELON FLEX families of Endoscopic Linear Cutters (articulating and straight) 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, Black reload. The modifications described in this submission do not affect the

intended use of the device or alter the fundamental scientific technology of the device. The summary information that results from the design control process serve as the basis for this submission along with the required elements of a 510(k) found in 21 CFR 807.87.

Performance Data

Ex-vivo (bench) testing was performed to ensure that the devices perform as intended and meet design specifications. Device performance was assessed against the design requirements and included process verification and design verification.

Conclusion

The Subject device, Echelon Endoscopic Linear Cutter Reload, Black, is substantially equivalent to the legally marketed Predicate device based on intended use, technological characteristics, and performance testing.

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

October 18, 2013

Ethicon Endo-Surgery, LLC
Ethicon Endo-Surgery, Inc.
Christina Canter
4545 Creek Road
Cincinnati, Ohio 45242

Re: K131663
Trade/Device Name: Echelon Endoscopic Linear Cutter Reload, Black
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 13, 2013
Received: September 16, 2013

Dear Ms. Canter:

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 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.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K131663

Device Name: Echelon Endoscopic Linear Cutter Reload, Black

INDICATION FOR USE

The ECHELON and ECHELON FLEX families of Endoscopic Linear Cutters (articulating and straight) 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131663