MAR 2 9 2013

510(k) Summary

K130653

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

Contact Carol Hubbard
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Ethicon Endo-Surgery, Inc.
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Date Prepared March 8, 2013

Device Name Trade Name: Echelon Flex Powered Articulating Endoscopic Linear Cutters
Common or Usual Name: Cutter/Stapler
Classification Name: Staple, Implantable; Stapler, Surgical

Predicate Device Echelon Flex Powered Articulating Endoscopic Linear Cutters (cleared under K110385)

Device Description The Echelon Flex Powered 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 three shaft lengths: compact, 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 instruments are shipped without a staple cartridge and must be loaded prior to use. The instrument has a safety lock-out feature that is designed to prevent an instrument without a cartridge or a used cartridge from being fired.

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 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°.

The modification described in this submission does not affect the intended use of the device or alter the fundamental scientific technology of the device, and 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 tests (bench) were 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, design verification and design validation.

Testing for all materials is in accordance with the standards AAMI/ANSI/ISO 10993-1:2009 and on FDA General Program Memorandum #G95-1: Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing."

Conclusion The Ethicon Endo-Surgery Echelon Flex Powered Articulating Endoscopic Linear Cutters are substantially equivalent to the legally marketed Predicate device based upon 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

Ethicon Endo-Surgery, LLC
% Ethicon End-Surgery, Incorporated
Ms. Carol Hubbard
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

Letter dated: March 29, 2013

Re: K130653
Trade/Device Name: Echelon Flex™ Powered Articulating Endoscopic Linear Cutters
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 08, 2013
Received: March 12, 2013

Dear Ms. Hubbard:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K130653

Device Name: Echelon Flex™ Powered Articulating Endoscopic Linear Cutters

INDICATION 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.

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

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130653