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510(k) Summary

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

JUN 26 2008

Contact Abhilasha Mukherjee, RAC
Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
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Date Prepared April 21, 2008

Device Name Trade Name: Echelon Endoscopic Linear Cutters (Articulating and Straight)
Common or Usual Name: Cutter/Stapler
Classification Name: Stapler, Surgical / Staple, Implantable

Regulatory Information

Regulation Number:	21 CFR § 878.4800
Regulation Name:	Stapler, Surgical
Regulatory Class:	I
Product Code:	GAG

Regulation Number:	21 CFR 878.4750
Regulation Name:	Staple, Implantable
Regulatory Class:	II
Product Code:	GDW

Predicate Device ENDOPATH Endocutter 60 Endoscopic Linear Cutters (cleared under K051002 and expanded indications cleared under K070887).

Device Description The Echelon Endoscopic Linear Cutters (Articulating and Straight) are sterile, single patient use instruments that simultaneously cut and staple tissue. 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 shafts for both the articulating and straight instruments can rotate freely in either direction. In addition, the Echelon Articulating Endoscopic Linear Cutters incorporate an articulation mechanism, which enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

The instruments are shipped without a cartridge and must be loaded prior to use. The instruments' lock-out feature is designed to prevent a used cartridge from being refired.

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Indications for Use The Echelon 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 technological characteristics of the Echelon Straight Endoscopic Linear Cutters are similar to the predicate device except for some changes in the ergonomic features. The Echelon Articulating Endoscopic Linear Cutters incorporate a new articulation mechanism as compared to the predicate device. The articulation mechanism enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

Performance Data Bench testing and preclinical laboratory evaluation in an animal model was performed to demonstrate that the devices will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Abhilasha Mukherjee, RAC
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K081146
Trade/Device Name: Echelon Endoscpic Linear Cutters (Articulating and Straight)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: April 21, 2008
Received: April 22, 2008

Dear Abhilasha Mukherjee:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K081146

Indications for Use

510(k) Number (if known): K081146

Device Name: **Echelon Endoscopic Linear Cutters (Articulating and Straight)**

Indications for Use:

The Echelon 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081146

(Posted November 13, 2003)