K080839

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510(k) Summary

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

MAY 21 2008

Contact Ruth Ann Wood, R.N., B.A., M.A., RAC
Senior Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
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Date Prepared March 24, 2008

Device Name Trade Name: Echelon™ Gray Cartridge—45mm

Common or Usual Names: Endoscopic and Accessory

Classification Names:
Implantable Staple [21 CFR 878.4750 (GDW)]

Predicate Devices ENDOPATH Endocutter Gray Cartridge clear under K033269 on December 10, 2003. ENDOPATH Endocutter 60 Endoscopic Linear Cutter, cleared under K051002 on May 17, 2005. ENDOPATH Endocutter 60 Endoscopic Linear Cutter, cleared under K070887 on May 25, 2007.

Device Description

The Echelon devices are sterile, single-use instruments that deliver staples while simultaneously dividing tissue between rows. These devices may be used in either open or Endoscopic procedures, depending upon the design. The device is intended for use in transection and resection of tissue for various open or minimally invasive surgical procedures. They are intended for use in the creation of anastomoses in these procedures. The instruments are reloadable and, as such, they may be reloaded with various cartridges depending on the thickness of tissue that is to be transected or resected.

The Echelon Gray cartridge is a storage case that contains implantable staples. The cartridge is loaded into an Echelon instrument. When the instrument is deployed, it cuts a surgical wound while simultaneously delivering the staples into the tissue. As in the predicate ETS Gray cartridge, the Echelon Gray cartridges will be available in 45mm lengths. There are 70 staples in the 45mm length cartridge.

Cartridges deliver the staples in a predetermined staple row configuration or pattern in relation to the cut line. The staple row configurations of both the predicate and the new

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device have 6 staples, 3 staples on either side of the cut line. The staple row configuration (or pattern) of the predicate device and the new device is straight. That is to say, all 6 staples are of the same height and formation.

Indications for Use The Echelon Ensoscopic Linear Cutters, Staplers and Reloads are intended for transection, resection, and/or 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 cartridge is for use on thin tissues such as mesentary and has a nominal closed staple height of .75 mm. The purpose of the change is to provide physicians with additional cartridge selection in the Echelon family of products.

Performance Data. Bench testing was performed to demonstrate that the new device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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% Ethicon Endo-Surgery, Inc.
Ruth Ann Wood, R.N., B.A., M.A., RAC
Senior Associate, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K080839
Trade/Device Name: Echelon Gray Cartridge
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 24, 2008
Received: March 26, 2008

Dear Ms. Wood:

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

Indications for Use

510(k) Number (if known): K080839

Device Name: Echelon Gray Cartridge

Indications for Use:

The Echelon Endoscopic Cutters, Staplers and Reloads are intended for transection, resection, and/or 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)

Neil R. P. Ogden for mtn

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

510(k) Number K080839

(Posted November 13, 2003)