DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2007

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Mr. Dennis Hahn
Director, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K070887
Trade/Device Name: ENDOPATH and Echelon Linear Cutter and Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 29, 2007
Received: March 30, 2007

Dear Mr. Hahn:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K070857

Device Name: **ENDOPATH® and Echelon Linear Cutters and Staplers**

ENDOPATH® ETS Endoscopic Linear Cutter, ETS-Flex Endoscopic Articulating Linear Cutter (and Reloads):

The ENDOPATH ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter has application in general, gynecologic, urologic, and thoracic surgery for transection, resection, and/or creation of anastomoses. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

ENDOPATH® ETS45 Endoscopic Linear Cutter, ETS-Flex45 Endoscopic Articulating Linear Cutter, ETS Compact Flex45 Articulating Linear Cutters (and Reloads):

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating 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.

ENDOPATH® ETS-Flex45 No-Knife Endoscopic Articulating Linear Stapler, ETS Compact-Flex45 No-Knife Articulating Linear Stapler (and Reloads):

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers 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.

ENDOPATH® ETS-Flex60 Endoscopic Articulating Long Linear Cutter and Reloads:

The ENDOPATH ETS Flex60 Endoscopic Articulating Long Linear Cutter is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. It can be used with staple line or tissue buttressing materials. The instrument may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Indications for Use

510(k) Number (if known): K070887

Device Name: **ENDOPATH and Echelon Linear Cutters and Staplers**

ENDOPATH® EZ45 Endoscopic Linear Cutter (and Reloads):
The ENDOPATH EZ45 Endoscopic Linear Cutter has application in multiple open and other minimally invasive surgical procedures for transection, resection, and/or creation of anastomoses. 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.

ENDOPATH® EZ45 No-Knife Endoscopic Linear Stapler (and Reloads):
The ENDOPATH EZ45 No-Knife Endoscopic Linear Stapler has application in multiple open or other minimally invasive surgical procedures for transection and resection. 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.

ENDOPATH® Thoracic Endoscopic Linear Cutter (and Reloads):
The ENDOPATH EZ45 Thoracic Endoscopic Linear Cutter has application in thoracic surgery or other minimally invasive surgical procedures for transection, resection, and/or creation of anastomoses. They can be used with staple line buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Echelon60 Endoscopic Linear Cutters and Reloads:
The Echelon60 Endoscopic Linear Cutter is 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 instrument 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)

(Posted November 13, 2003)

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

510(k) Number K070887