ENDOPATH™ and PROXIMATE™ Linear Cutters and Staplers 510(k) Summary of Safety and Effectiveness

Company:
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact:
Name: Doug Kentz
Title: Sr. Regulatory Affairs Associate

Date Prepared:
March 8, 2002

Name of Device:
Trade Name: ENDOPATH and PROXIMATE Linear Cutters and Staplers
Classification Name: Endoscope and Accessories, Implantable Staples, General & Plastic Surgery

Predicate Devices:

ENDOPATH and PROXIMATE Linear Cutters and Staplers and Reloads are cleared under K821994, K843034, K890841, K843034, K892927, K932434, K935064, K961390, K970720, K980023, K980815, K002398.
Auto Suture™ ENDO GIA II and ENDO GIA Universal (United States Surgical Corporation) cleared under K913802.

Device Description:

The ENDOPATH and PROXIMATE Linear Cutter models are sterile single use instruments that deliver staples while simultaneously dividing tissue between rows. The ENDOPATH No-Knife Stapler and PROXIMATE Stapler models are sterile single use instruments that deliver staples, but do not cut. Depending upon the particular model, they deliver 2 to 3 staggered rows of staples, 2 double-staggered rows, or 2 triple-staggered rows of staples. Staple line lengths vary between 35 mm and 100 mm. These instruments may be used in either open or endoscopic procedures, depending upon the design. Some instruments are reloadable and, if so, they may be reloaded with various reloads (i.e. vascular/thin, standard, thick) depending on the thickness of tissue that is to be transected or resected. Vascular models use specific vascular reload cartridges. The instruments may be reloaded a number of times according to product insert instructions for a maximum number of firings per instrument. Some instruments have articulating heads and flex features. The length of the shaft may vary as well. A safety lock-out

feature on linear cutter instruments prevents a used reload from being fired again. The common element among all these instruments is that they are all mechanical surgical stapling devices.

Intended Use:

The ENDOPATH and PROXIMATE Linear Cutters and Staplers are intended for use in multiple open or minimally invasive surgical procedures for the transection and resection of tissues. Linear cutters are also intended for creation of anastomoses in these procedures. Specific indications are provided in specific instrument product insert labeling.

Technological Characteristics:

The ENDOPATH and PROXIMATE Linear Cutters and Staplers are similar to the predicate devices in that they have the same intended use and are single-use sterile devices.

Performance Data

Animal testing demonstrated satisfactory performance of the ENDOPATH and PROXIMATE Linear Cutters and Staplers to support the revised product insert labeling. The performance data and information in this submission demonstrate that these devices, when used in accordance with directions for use with respect to tissue thickness, can be used in procedures where pulmonary vessels are encountered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 5 2002

Mr. Doug Kentz, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242-2839

Re: K020779
Trade/Device Name: ENDOPATH™ and PROXIMATE™ Linear Cutters and Staplers
Regulation Number: 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 8, 2002
Received: March 11, 2002

Dear Mr. Kentz:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020779

510(k) Number (if known): _____

Device Name: ENDOPATH™ and PROXIMATE™ Linear Cutters and Staplers

Indications for Use:

The ENDOPATH ETS Endoscopic Linear Cutter and ETS FLEX Endoscopic Articulating Linear Cutter have application in general, gynecologic, urologic, and thoracic surgery for transection, resection, and/or creation of anastomoses.

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS Flex45 Endoscopic Articulating Linear Cutters , 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 (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

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 (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

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, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The ENDOPATH EZ45 No-Knife Endoscopic Linear Stapler has application in multiple open or other minimally invasive surgical procedures for transection and resection, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The ENDOPATH EZ45 Thoracic Endoscopic Linear Cutter has application in thoracic and other minimally invasive surgical procedures for transection, resection, and/or creation of anastomoses, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The PROXIMATE ACCESS 55 Articulating Linear Staplers have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection and resection of tissues.

The PROXIMATE Linear and Vascular Linear Cutters with Safety Lockout have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The PROXIMATE Linear Four Row Stapler with Safety Lockout have application in gastrointestinal and thoracic surgery for transection and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The PROXIMATE Reloadable Linear Stapler has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.

The PROXIMATE Reloadable Vascular Linear Stapler has application for use on internal tissue that can easily be compressed to 1.0 mm in thickness. The staplers may also be used to ligate pulmonary vessels.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N. Milhous

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

510(k) Number K020779