



K 980023

MAR 18 1998

4545 CREEK ROAD  
CINCINNATI, OH 45242-2839

## 510(k) Summary of Safety and Effectiveness

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**Contact** Lorri Chavez, Project Manager  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242  
Telephone: (513) 483-3513

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**Date prepared** January 2, 1998

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**Device** Name: **ENDOPATH® and PROXIMATE® Linear Cutters**  
Classification Name: Endoscope and Accessories  
Common Name: Linear Cutter  
Trade Name/Proprietary Name: ENDOPATH® and PROXIMATE® Linear Cutters

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**Legally marketed devices** Linear Stapler (LSR) - Rigid (K821994);  
Disposable Linear Cutter (K843034);  
PROXIMATE® Linear Cutter Thick Tissue Instrument (K892927);  
ENDOPATH® Endoscopic Linear Cutter with Safety Lock-Out and  
Reloading Unit (K915099);  
ENDOPATH® Reloadable Linear Cutter with Safety Lock-Out and  
Reloading Unit (K930934);  
Modified ENDOPATH® Endoscopic Linear Cutter with Safety Lock-Out and  
Reloading Unit (No-Row) (K935064);  
Modified ENDOPATH® Endoscopic Reloadable Linear Cutter with Safety  
Lockout and Reload Unit (K945202);

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## 510(k) Summary of Safety and Effectiveness, Continued

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<b>Legally marketed devices, cont'd</b>	New Indication for ENDOPATH® and PROXIMATE® Linear Cutters and Staplers (K951546); ENDOPATH® EZ-RF Linear Cutter and Coagulation Device (K961264); ENDOPATH® ETS Endoscopic Linear Cutter and ETS-FLEX Endoscopic Articulating Linear Cutter Devices (K961390); and, ENDOPATH® EZ45 Endoscopic Linear Cutter and ENDOPATH® EZ45 No Knife Endoscopic Linear Stapler (K970720).
<b>Device description</b>	All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) have not changed from the above-mentioned 510(k)s.
<b>Intended use</b>	The ENDOPATH® and PROXIMATE® Linear Cutters are intended for transection, resection, and/or creation of anastomoses.
<b>Indications statement</b>	The ENDOPATH® and PROXIMATE® Linear Cutter indication statements have not changed from the above-mentioned 510(k)s.
<b>Technological characteristics</b>	The ENDOPATH® and PROXIMATE® Linear Cutter technological characteristics have not changed from the above-mentioned 510(k)s.
<b>Performance data</b>	The ENDOPATH® and PROXIMATE® Linear Cutters' performances have not changed from the above-mentioned 510(k)s.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

Ms. Lorri Chavez  
Project Manager  
Regulatory Affairs  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242-2839

Re: K980023  
Trade Name: Endopath® and Proximate® Linear Cutters  
Regulatory Class: II  
Product Code: GCJ  
Dated: January 2, 1998  
Received: January 5, 1998

Dear Ms. Chavez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A ~~substantially equivalent determination assumes compliance with~~ the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*for Stephen Rocks*

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

Enclosure

## Indications for Use Statement (App. B)

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**Statement**

Indications for Use Statement:

510(k) Number: K 980023

Device Name: ENDOPATH® and PROXIMATE® Linear Cutters

K821994: The Disposable Linear Stapler has application in abdominal, thoracic, and pediatric surgery for resection and transection of internal tissues. The total thickness of the tissues being connected must be within the range of 1.0 to 3.0 mm.

K843034: The PLC50 has application in abdominal, pediatric and thoracic surgery for resection, transection and creation of anastomoses.

K892927: The LCT75 has application in gastrointestinal and thoracic surgery for resection, transection and creation of anastomoses. Cartridges for the standard (PLC75) and Thick Tissue (LCT75) are interchangeable within these instruments.

K915099: The ENDOPATH Endoscopic Linear Cutter with Safety Lock-out has applications multiple open or endoscopic procedures for the transection, resection and creation of anastomosis.

K930934: The ENDOPATH Endoscopic Reloadable Linear Cutter with Safety Lock-Out has application in gastrointestinal and thoracic surgery for transection, resection and creation of anastomoses.

K935064: The ENDOPATH Endoscopic Linear Cutter with Safety Lock-Out has application in multiple open or endoscopic procedures for the transection, resection, and creation of anastomoses.

K945202: The ENDOPATH Endoscopic Reloadable Linear Cutter with Safety Lock-Out has multiple open or endoscopic procedures for transection, resection and/or creation of anastomoses.

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## Indications for Use Statement (App. B), Continued

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Statement,  
continued

K951546: [Verbiage for all of the various indication statements remain the same, plus] ... and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

K961264: The ENDOPATH® EZ-RF Linear Cutter and Coagulation device has applications in open and minimally invasive surgical procedures for coagulation, transection, and resection of tissue. **The bipolar feature is to be used only with the ERBE ERBOTOM ICC 350 or the Valleylab Force 2 electro-surgical generators.**

K961390: The ENDOPATH ETS Endoscopic Linear Cutter and ETS-FLEX Endoscopic Articulating Linear Cutter have application in general, urologic, gynecologic, and thoracic surgery for transection, resection, and/or creation of anastomoses.

K970720: The ENDOPATH EZ45 Endoscopic Linear Cutter has application in multiple open or 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.

*and*

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 buttressing materials, such as bovine pericardium.

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(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K980023

Prescription Use X  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_