MAY 17 2005 K051002



# 510(k) Summary

**Company** Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

**Contact** Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
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**Date Prepared** April 19, 2005

**Device Name** Trade Name: ENDOPATH® Endocutter 60 Endoscopic Linear Cutter
Common or Usual Name: Linear Cutter
Classification Name: Endoscope and Accessories and Implantable Staples [21 CFR 876.1500 (KOG) and 21 CFR 878.4750 (GDW)]

**Predicate Device** ENDOPATH® Linear Cutters and Staplers

**Device Description** These instruments are all mechanical surgical stapling devices. The ENDOPATH Endocutter 60 Endoscopic Linear Cutter models are sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows. These instruments may be used in either open or endoscopic procedures. The devices will be available in three shaft lengths: standard, compact and long, and will be furnished without a cartridge. Cartridges for the Endocutter 60 devices will be available in sizes that correspond to the thickness of tissue that is to be transected or resected: white (vascular/thin), blue (standard), gold (thick, less dense) and green (thick).

**Indications for Use** The ENDOPATH Endocutter 60 Endoscopic 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.

**Technological Characteristics** The device incorporates a new 60mm cartridge design; new enhanced compression system; rigid anvil and E-beam with robust, one-piece design; wide jaw aperture for easy tissue positioning and manipulating; and ergonomic features for one-handed use (ability to clamp, fire and release with automatic knife return). The ENDOPATH Endocutter 60 device will be available in three shaft lengths: standard, compact and long. Compatible cartridges come in four sizes to accommodate various tissue thicknesses. The gold cartridge is an additional size added to the product line. The gold cartridge staple wire diameter is identical to the existing blue cartridge staple wire diameter, with a longer staple leg length for thicker indicated tissue.

**Performance Data** Bench testing and preclinical laboratory evaluations were performed to demonstrate that the device will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Ms. Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery Incorporated
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K051002
Trade/Device Name: ENDOPATH® Endocutter60 Endoscopic Linear Cutter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 19, 2005
Received: April 20, 2005

Dear Ms. Abernathy:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051002



# Indications for Use

510(k) Number (if known): _____

Device Name: **ENDOPATH® Endocutter 60 Endoscopic Linear Cutter**

Indications for Use:

The ENDOPATH Endocutter 60 Endoscopic 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.

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|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(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)*

K051002