

510(k) Summary

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

JUL - 3 2006

Contact Tom Morris
Quality Systems/Regulatory Affairs Project Manager
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Date Prepared June 13, 2006

Device Name Trade Name: ENDOPATH Linear Cutters and Staplers
Common or Usual Name: Staple, Implantable
Classification Name: Staple, Implantable [21 CFR 878.4750 (GDW)]

Predicate Device ENDOPATH Linear Cutters and Staplers

Device Description

Endocutter 60 Endoscopic Linear Cutter: EC60, SC60, LONG60

Sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows. ECHELON 60-instruments with white, blue, gold, and green reloads deliver two triple-staggered rows of staples. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 60mm long and a cut line that is approximately 57mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

ETS45 Endoscopic Linear Cutter: TSB45, TSG45, 6SB45

ETS-Flex45 Endoscopic Articulating Linear Cutter: ATB45, ATG45, 6TB45, LONG45A

ETS Compact Flex45 Articulating Linear Cutters: SCB45, SCG45, 6CB45

Sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows. Instruments with blue (standard) reloads deliver two double- or triple-staggered rows of staples; instruments with green (thick) reloads deliver two double-staggered rows of staples only. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45mm long and a cut line that is approximately 41mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on some instruments enables bilateral movement of the instrument jaws.

ETS-Flex45 No-Knife Endoscopic Articulating Linear Stapler: NAB45, NAG45

ETS Compact-Flex45 No-Knife Articulating Linear Stapler: NSB45, NSG45

Sterile, single patient use instruments. Instruments with blue (standard) reloads deliver two double- or triple-staggered rows of staples; instruments with green (thick) reloads deliver two double-staggered rows of staples only. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on the instruments enables bilateral movement of the instrument jaws.

EZ45 Endoscopic Linear Cutter: ET45B, ET45G

Sterile, single patient use instrument that delivers two double-staggered rows of staples while simultaneously dividing the tissue between rows. The instrument is designed for use in procedures with or without insufflation. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45mm long and a cut line that is approximately 41mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

EZ45 No-Knife Endoscopic Linear Stapler: NK45B, NK45G

Sterile, single patient use instrument that delivers two double-staggered rows of staples. The instrument is designed for use in procedures with or without insufflation. The instrument's safety lock-out feature is designed to prevent a used reload from

being refired. The instruments have a staple line that is approximately 45mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

Thoracic Endoscopic Linear Cutter: EZ45B, EZ45G

Sterile, single patient use instrument that delivers two double-staggered rows of staples while simultaneously dividing the tissue between rows. The instrument is designed for use in procedures without insufflation. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instrument has a staple line that is approximately 45mm long and a cut line that is approximately 41mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

Indications for Use

Endocutter 60 Endoscopic Linear Cutter: EC60, SC60, LONG60

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.

ETS45 Endoscopic Linear Cutter: TSB45, TSG45, 6SB45

ETS-Flex45 Endoscopic Articulating Linear Cutter: ATB45, ATG45, 6TB45, LONG45A

ETS Compact Flex45 Articulating Linear Cutters: SCB45, SCG45, 6CB45

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.

ETS-Flex45 No-Knife Endoscopic Articulating Linear Stapler: NAB45, NAG45

ETS Compact-Flex45 No-Knife Articulating Linear Stapler: NSB45, NSG45

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.

EZ45 Endoscopic Linear Cutter: ET45B, ET45G

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.

EZ45 No-Knife Endoscopic Linear Stapler: NK45B, NK45G

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.

Thoracic Endoscopic Linear Cutter: EZ45B, EZ45G

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 and can be used with staple line buttressing materials.

Technological Characteristics The technological characteristics are identical to the predicate devices. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the Directions for Use and Indications Statements.

Performance Data Ethicon Endo-Surgery conducted animal testing (Section 19) and a clinical literature search (Section 20) to establish the use of the stapling devices (No-Knife ETS and EZ products only) in the open Left Atrial Appendage Exclusion procedure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ethicon Endo-Surgery Inc.
% Mr. Tom Morris, MBA, CQE
Quality Systems/Regulatory Affairs
Project Manager
4545 Creek Road
Cincinnati, Ohio 45242

Re: K061156

Trade/Device Name: ENDOPATH device family
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 25, 2006
Received: April 26, 2006

Dear Mr. Morris:

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.

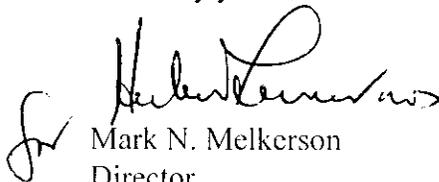
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized initial "M" to the left.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7061156

Indications for Use

510(k) Number (if known): K061156

Device Name: **ENDOPATH device family**

Endocutter 60 Endoscopic Linear Cutter: EC60, SC60, LONG60

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.

ETS45 Endoscopic Linear Cutter: TSB45, TSG45, 6SB45

ETS-Flex45 Endoscopic Articulating Linear Cutter: ATB45, ATG45, 6TB45, LONG45A

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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.

ETS-Flex45 No-Knife Endoscopic Articulating Linear Stapler: NAB45, NAG45

ETS Compact-Flex45 No-Knife Articulating Linear Stapler: NSB45, NSG45

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.

EZ45 Endoscopic Linear Cutter: ET45B, ET45G

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.

EZ45 No-Knife Endoscopic Linear Stapler: NK45B, NK45G

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.

Thoracic Endoscopic Linear Cutter: EZ45B, EZ45G

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 and can be used with staple line buttressing materials.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

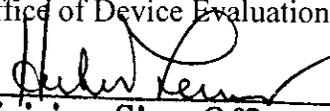
AND/OR

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)

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(Posted November 13, 2003)



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

510(k) Number K061156