

510(k) Summary

SEP 25 2006

Company Ethicon Endo-Surgery, Inc.
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Date Prepared June 22, 2006

Device Name Trade Name: Ethicon Endo Surgery® Endoscopic Suturing System
Common or Usual Name: Endoscopic Suturing System
Classification Name: Endoscopes and accessories
[21 CFR 876.1500 (KOG)]

Predicate Devices Bard® EndoCinch™ Suturing System (K003956)
ENDOPATH® Endoscopic Tissue Fastening System (K972679)
LSI Solutions Flexible Suture Placement Device and Acc. (K011016)

Device Description The Ethicon Endo Surgery® Endoscopic Suturing System (ESS) is a sterile, single-use, disposable suturing system for use in gastrointestinal procedures. It consists of the following components:

- 1 Endoscopic suturing device (ESD)
- 2 ESD mounting tool
- 3 Four (4) needle/ suture packs each in a needle-loading tool
- 4 Endoscopic knotting element device (KED)
- 5 Four (4) knotting element implants
- 6 KED handle stop
- 7 KED threading tool

The endoscopic suturing device (ESD) is the suturing component of the system. The ESD is mounted on commercially available flexible gastrointestinal endoscopes with 9.9-10.5 mm outer diameter and minimum 2.8 mm working channel such as the Olympus GIF-100 or GIF-140. Under endoscopic visualization, the ESD enables the physician to create continuous or interrupted suture lines in soft tissue. The ESD consists of a suturing assembly activated through a flexible control shaft terminating in an ergonomic handle. The suture assembly consists of a tissue recess and needle/suture assembly. The needle/suture assembly is loaded in the ESD prior to use with the supplied needle-loading tool. The suturing assembly of the ESD contains a tissue recess, which allows access to an amount of tissue necessary to achieve tissue bites. After tissue is located in the recess of the suturing assembly, the handle is squeezed. The handle is connected to a control cable, which actuates the needle/suture assembly, causing a circular needle, with suture attached, to be partially rotated within the suturing assembly. Following a full revolution (approximately 4 strokes), the needle returns to a stored position within the suturing assembly. The device is repositioned to perform

another tissue bite or stitch. Following completion of the last stitch, the endoscope and ESD are removed. By spacing the stitches appropriately and then tightening the suture line, tissue approximation will be achieved.

The knotting element device (KED) is the suture terminating and cutting component of the system. The KED is used for the endoscopic termination of two ends of suture. The KED consists of an end-effector (a suture cutter and a two-piece knotting element implant) activated through a flexible control shaft terminating in an ergonomic handle. The knotting element implant consists of a mating polymer inner lock and outer washer sleeve, which is threaded with suture and crimped together through the actuation of the device. The two ends of the suture are threaded through the knotting element with the assistance of the KED threading tool and, while external tension is held on the ends of the suture lines, the device is passed through the working channel, over the suture to the termination location inside the body. The suture line is tightened, and the handle is activated to release the knotting element implant and to cut the suture line leaving approximately 1 cm of suture material and the knotting element implant. The mating parts of the knotting element implant secure the two ends of the suture. This fixation replaces the knot component of suture. The device and scope are then free of the suture line and can be removed.

The device is available with a variety of suture materials. The materials are described in the following table.

Trade Name	Material Type	Brief Description
Pronova [®]	Poly (hexafluoropropylene-VDF)	Nonabsorbable, monofilament
Prolene [®]	Polypropylene	Nonabsorbable, monofilament
Coated Vicryl [®] Coated Vicryl [®] Plus Antibacterial	Polyglactin 910	Absorbable, braided with and without antibacterial coating
PDS [®] II	Polydioxanone	Absorbable, monofilament
Monocryl [®] Monocryl [®] Plus Antibacterial	Poliglecaprone 25	Absorbable, monofilament with and without antibacterial coating

The Ethicon Endo Surgery[®] Endoscopic Suturing System (ESS) is packaged sterile for single patient use. This system is commonly referred to by the product code EES01. Ethicon Endo Surgery also intends to market the ESD and KED separately. These product codes are yet to be determined.

Indications for Use The Ethicon Endo Surgery® Endoscopic Suturing System (ESS) is indicated for endoscopic placement of suture(s) and approximation of soft tissue.

Technological Characteristics The Ethicon Endo Surgery® Endoscopic Suturing System (ESS) is similar to the design of the predicate device, the Bard® EndoCinch™ Suturing System. Both devices mount to a commercially available endoscope and use needle and suture to endoscopically approximate soft tissue. Both devices include an endoscopic means of suture termination. The new device is different from the predicate device in that it uses a curved instead of a straight needle. In addition, the new device utilizes a tissue recess instead of a vacuum chamber in order to access soft tissue for suturing and approximation. A second predicate, LSI Solutions Flexible Suture Placement Device, utilizes a tissue recess similar to the new device. In addition, the LSI device contains an optional vacuum function.

Performance Data. Bench testing was performed to demonstrate that the new device performs as intended. A clinical literature search was also conducted and the literature supports the intended use of the new device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 25 2006

Ethicon Endo-Surgery Inc.
% Mr. Tom Bosticco
Project Manage, Quality Systems &
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4545 Creek Road
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Re: K061770

Trade/Device Name: Ethicon Endo Surgery® Endoscopic Suturing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: August 29, 2006
Received: August 30, 2006

Dear Mr. Bosticco:

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.

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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): K061770

Device Name: Ethicon Endo Surgery® Endoscopic Suturing System

Indications for Use:

The Ethicon Endo Surgery® Endoscopic Suturing System is indicated for endoscopic placement of suture(s) and approximation of soft tissue.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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(Posted November 13, 2003)

510(k) Number K061770