

K972679

SEP 19 1997

## Appendix A: 510(k) Summary of Safety and Effectiveness

**Statement**

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

**Device description**

The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) consists of the SEW E-Z Reload Unit, the SEW E-Z Suture Assistant, and the SEW-RIGHT Self Righting Needle Holder (see Instructions for Use for the ENDOPATH® SEW-RIGHT Self Righting Needle Holder).

The SEW E-Z Reload Unit is a sterile, single patient use device consisting of a knot/grasper element comprised of an ETHIBOND EXCEL polyester suture (in sizes 0 or 2-0) with a pre-tied knot and a curved needle attached. The knot/grasper element is contained inside a carrier for loading the SEW E-Z Suture Assistant.

The SEW E-Z Suture Assistant is a sterile, single patient use instrument designed to assist endoscopically in approximating tissue and in placing a suture and a secure knot intracorporeally. It is designed for use with a 5.4 mm trocar or a larger trocar with use of reducer cap.

The instrument has two levers: the control lever facilitates loading the instrument and opening and closing the grasper; the knot deployment lever contains a ratchet mechanism for controlled deployment of the pre-tied knot.

The instrument contains a shaft retractor button on both sides of the instrument for unloading and reloading knot/grasper elements.

The instrument may be reloaded during a single procedure. Do not reload the instrument for more than a total of eight knot deployments per instrument.

*Continued on next page*

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

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### Device description (continued)

ETHIBOND EXCEL Polyester Suture is a nonabsorbable, braided, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component. ETHIBOND EXCEL suture is uniformly coated with polybutylate or poly [oxy-1, 4 butanediyl oxy 91, 6 hexanediyl)].

The highly adherent coating is a relatively nonreactive nonabsorbable compound which acts as a lubricant to mechanically improve the physical properties of the uncoated suture by improving ease of passage through tissues and by providing overall handling qualities as contrasted to the braided, uncoated fiber.

ETHIBOND EXCEL sutures are braided for optimal handling properties and, for good visibility in the surgical field, are dyed green. ETHIBOND EXCEL sutures meet all requirements established by the United States Pharmacopeia (U.S.P.) for nonabsorbable sutures.

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**Intended use** For approximation of soft tissues.

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**Indications statement** The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) is intended for use in minimally invasive surgical applications where soft tissue is being approximated with interrupted stitches.

ETHIBOND EXCEL Polyester Suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

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**Technological characteristics** The technological characteristics of the New Device is the same as the Predicate Devices.

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

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**Performance  
data**

Bench testing and pre-clinical laboratory evaluations were performed to ensure that the device could be used as designed.

The studies demonstrated that the ETFS system facilitated laparoscopic suturing, the ASD, together with the KEC, allowed for one-handed knot deployment, knot security appeared adequate, and the Self-Right Needleholder (Modified ENDOPATH® 5mm Reusable Needleholder) allowed for rapid needle orientation and facilitated needle management.

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**Conclusion**

**Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the New Device is substantially equivalent to the Predicate Devices under the Federal Food, Drug and Cosmetic Act.**

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**Contact**

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

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**Date**

July 15, 1997

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

SEP 19 1997

Re: K972679  
Trade Name: Endopath® Endoscopic Tissue Fastening System  
Regulatory Class: Class II  
Product Code: GAT  
Dated: July 15, 1997  
Received: July 16, 1997

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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 requirements, as set forth in the Quality System

Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used in the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

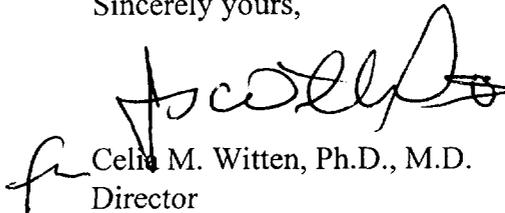
1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. 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

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and cursive, with a large initial "C" and "W".

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

## Appendix B: Indications for Use Statement

Statement

Indications for Use Statement:

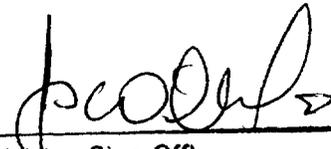
510(k) Number: K972679

Device Name: ENDOPATH® Endoscopic Tissue Fastening System (ETFS)

Indications for Use: The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) is intended for use in minimally invasive surgical applications where soft tissue is being approximated with interrupted stitches.

ETHIBOND EXCEL Polyester Suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Prescription Use X  
(Per 21 CFR 801.109)

  
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(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K972679