ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

K980022

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

# 510(k) Summary of Safety and Effectiveness

MAR - 9 1998

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| **Contact** | Lorri Chavez, Project Manager<br>Ethicon Endo-Surgery, Inc.<br>4545 Creek Road<br>Cincinnati, Ohio 45242<br>Telephone: (513) 483-3513 |
| **Date** | January 2, 1998 |
| **Device** | Name: **ENDOPATH® Endoscopic Tissue Fastening System (ETFS)**<br>Classification Name: Manual Surgical Instrument<br>Common Name: Knot Tying Instrument<br>Trade Name/Proprietary Name: ENDOPATH® Endoscopic Tissue Fastening System (ETFS) |
| **Legally marketed device** | ENDOPATH® Endoscopic Tissue Fastening System (ETFS) (K972679). |
| **Device description** | All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) have not changed in design or manufacture from 510(k) #972679. |
| **Intended use** | The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) is intended for use where soft tissue is being approximated. |
| **Indications statement** | The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) indication statement has not changed from 510(k) #972679. |

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

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| **Technological characteristics** | The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) technological characteristics have not changed from 510(k) #972679. |
| **Performance data** | The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) performance has not changed from 510(k) #972679. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1998

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

Re: K980022
Trade Name: ENDOPATH® Endoscopic Tissue Fastening System (ETFS)
Regulatory Class: II
Product Code: GCJ and GAT
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 (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 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 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)

**Statement**

Indications for Use Statement:

510(k) Number: K 980022

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

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)**

**(Division Sign-Off)**
**Division of General Restorative Devices**
**510(k) Number** K980022