OCT 14 1999

K992612

510(k) Summary of Safety and Effectiveness

Submitter

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

Contact

Edwin O. Billips

Date

August 2, 1999

Device Name

The Classification Name of this device is Manual Surgical Instrument; the Common Name is Knot Tying Instrument; and the Trade/Proprietary Name is ENDOPATH® Endoscopic Tissue Fastening System (ETFS) with Coated VICRYL®.

Predicate Device

Ethicon Endo-Surgery's ENDOPATH® Endoscopic Tissue Fastening System (ETFS)-K980022; Ethicon Endo-Surgery's ENDOPATH® Endoscopic Tissue Fastening System (ETFS)-K972679.

Device Description

The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) with Coated VICRYL® is a single patient use reloadable instrument that is intended for the use in minimally invasive surgical applications where soft tissue is being approximate with interrupted stitches. It is designed for use with a 5 mm trocar. The instrument is design for eight-knot deployments.

Intended use

The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) with Coated VICRYL® is intended for use in minimally invasive surgical applications where soft tissue is being approximate with interrupted stitches.

Continued on next page

510(k) Summary of Safety and Effectiveness,

Technological characteristics	The technological characteristics of the New Device are the same as those of the Predicate Devices. The ENDOPATH® Endoscopic Tissue Fastening System (ETFS) with Coated VICRYL® utilizes an absorbable suture to approximate soft tissue with interrupted stitches.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device performs as intended. The bench data and the animal studies demonstrated that the ENDOPATH® Endoscopic Tissue Fastening System (ETFS) with Coated VICRYL® facilitated laparoscopic suturing, allowed one-handed knot deployment, and provided a secured knot in soft tissue with interrupted stitches.
Conclusion	Based on (21 CFR §807) and the information provided herein, we conclude that the New Device is as safe, as effective, and performs as well as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Mr. Edwin O. Billips, RAC
Senior Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K992612
Trade Name: Endopath Endoscopic Tissue Fastening System with coated VICRYL®
Regulatory Class: II
Product Code: GCJ
Dated: August 2, 1999
Received: August 4, 1999

Dear Mr. Billips:

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 enclosures) 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K992612

Device Name: ENDOPATH Endoscopic Tissue Fastening System (ETFS) with Coa VICRYL

Indications For Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAG NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992612

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1