K 984240

JUN 22 1999

510(k) Summary of Safety and Effectiveness

Submitter

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

Contact

Jackie A. Strasser, MT (ASCP), MS
Regulatory Affairs Associate
Telephone (513) 786-7978 Fax (513) 786-7134

Date

November 23, 1998

New Device

- Name: ENDOPATH® Endoscopic Instruments
- Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Common Name: Laparoscopic Surgical Instruments
- Trade Name/Proprietary Name: ENDOPATH® Endoscopic Instruments

Legally marketed device

The Predicate Device legally marketed under K910831:
[Symbiosis] ENDOPATH Endoscopic Instruments

Device description

The ENDOPATH Endoscopic Instruments are sterile, single patient use instruments designed for use through appropriate ENDOPATH Surgical Trocars and FLEXIPATH® Flexible Surgical Trocars. The instruments have a rotating insulated shaft with a diameter of either 3mm, 5mm or 10mm. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. The ring handles are compressed and released to activate the instrument jaws or scissor blades. Each of the curved scissors and dissectors has a monopolar cautery connector that extends from the top of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and a proper generator.

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

Intended use	The ENDOPATH Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.
Technological characteristics	The technological characteristics of the New Device are the same as the Predicate Device.
Performance data	Pre-clinical data were used to evaluate the performance to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device in reliability and design. The performance evaluated are ergonomics of the handle and rotating knob tissue trauma, grasping, dissecting, cauterizing ability and cutting ability. From the date generated, it can be concluded that the New Device performs equivalent to the Predicate Device.
Conclusion	Based on the information provided herein and the Decision-Making Process Chart (Appendix E), we conclude that the New Device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 1999

Ms. Jackie A. Strasser, MT (ASCP), MS
Associate, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K984240
Trade Name: ENDOPATH® Endoscopic Instruments
Regulatory Class: II
Product Code: GEI
Dated: March 22, 1999
Received: March 24, 1999

Dear Ms. Strasser:

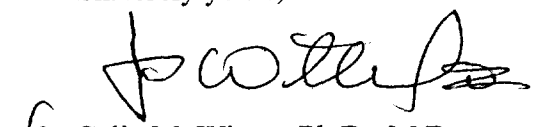
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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 A Indications for Use Statement

Statement

The following is the Indications for Use Statement:

510(k) Number: K 984240
Device Name: ENDOPATH Endoscopic Instruments

Indications for Use:

The ENDOPATH Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984240