AUG 21 [illegible] K971473

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® Dilating Tip Trocar consists of two main sub-assemblies: an obturator sub-assembly and a sleeve sub-assembly. The obturator consists of a sharp flat blade tip or pyramidal tip and a spring loaded shield. The shield is designed to cover the flat blade or pyramidal tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered. The sleeve subassembly has an inner gasket seal or flapper door seal and an outer gasket seal to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through the cannula during a surgical procedure. Some instruments are provided with a stopcock for insufflating the operative space and a flapper door lever to allow quick desufflation. Integral threads along the outside diameter of the cannula portion of the sleeve provide a retention mechanism to stabilize the sleeve in tissue. The ENDOPATH® Dilating Tip Trocar shall be provided in a variety of sizes from 3mm to 12mm in diameter and 65mm to 150mm in length.
Intended use	The intended use of the New Device is to establish a path of entry for minimally invasive instruments. Instruments provided with a stopcock are intended for insufflation of the operative space when the trocar is in place.
Indications statement	The ENDOPATH® Dilating Tip Trocar has application in general, thoracic, gynecologic, or other minimally invasive surgical procedures to establish a path of entry for minimally invasive instruments.

Continued on next page

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

Technological characteristics	The technological characteristics of the New Device are the same as the Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device in mating the obturator with the sleeve, insertion into the operative cavity, removal of the obturator from the sleeve, security of the sleeve in tissue, and maintenance of pneumoperitoneum of the operative space.
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 Device under the Federal Food, Drug and Cosmetic Act.
Contact	Ivan S. Placko Project Manager Regulatory Affairs Department Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Date	April 21, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ed Billips, RAC
Project Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

AUG 21 1997

Re: K971475
Trade Name: ENDOPATH® Dilating Tip Trocar
Regulatory Class: II
Product Code: GCJ
Dated: July 30, 1997
Received: July 31, 1997

Dear Mr. Billips:

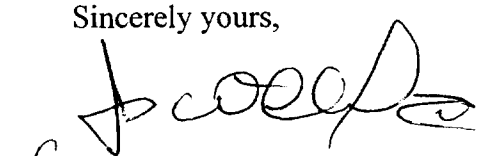
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Appendix B Indications for Use Statement

Statement

Following is the Indications for Use Statement:

510(k) Number: K971475

Device Name: ENDOPATH® Dilating Tip Trocar

Indications for Use:

The ENDOPATH® Dilating Tip Trocar has application in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for minimally invasive instruments.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971475

Prescription Use
(Per 21 CFR 801.109)