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

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

K973139

NOV 13 1997

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® Ultra-Retractor consists of a handle, a wide shaft, and a transparent blunt tip dissector (two instruments are available with a variation in the tip size). The blunt tip dissects tissue and creates a cavity that allows instrument passage. The wide shaft maintains the space created by the transparent tip. The tip is transparent to allow visualization during insertion, tunneling, and dissection. Also, the device is provided with a luer lock, located on the handle, for the attachment of suction or gas, such as CO_2, nitrogen, or air, as an aid for the removal of mist or smoke when used in combination with electrosurgery or ultrasonic devices and/or clearing the endoscope lens.

The instrument is compatible with a rigid endoscope that has maximum diameter of 5.5mm and is 290mm to 300mm in length.

Intended use

The ENDOPATH® Ultra-Retractor and Vessel Dissector are intended for use in dissecting and retracting in all types of surgical procedures requiring dissection and retraction of tissue.

Continued on next page

Vol II

510(k) Summary of Safety and Effectiveness, Continued

Indications statement	The ENDOPATH® Ultra-Retractor has application for the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal, and subcutaneous areas. The device may be used in all types of surgical procedures, requiring dissection and retraction of tissue. The Vessel Dissector has application for use in the blunt dissection of tubular structures such as veins, arteries, nerves, and ducts. The device may also be used in all types of surgical procedures requiring dissection of tissue.
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.
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	Lonnie Pace Project Manager Regulatory Affairs Department Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Date	August 18, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

Mr. Lonnie Pace
Project Manager, Regulatory Affairs Department
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K973139
Trade Name: Endopath® Ultra-Retractor and Endopath® Vessel Dissector
Regulatory Class: II
Product Code: GCJ
Dated: August 18, 1997
Received: August 21, 1997

Dear Mr. Pace:

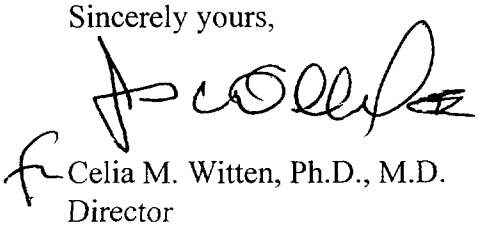
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 B Indications for Use Statement

Statement

Following is the Indications for Use Statement:

510(k) Number: K973139
Device Name:

Indications for Use:

The ENDOPATH® Ultra-Retractor has application for the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal and subcutaneous areas. The device may be used in all types of surgical procedures requiring dissection and retraction of tissue.

The Vessel Dissector has application for use in the blunt dissection of tubular structures such as veins, arteries, nerves and ducts. The device may also be used in all types of surgical procedures requiring dissection of tissue.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973139