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K972578

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® OPTIVIEW™ Optical Obturator and Sleeve consists of two main components: an obturator with an optical element and a trocar sleeve.

The optical obturator provides visualization of tissue as it passes through each layer by dilating and separating the tissue along its path of entry.

The sleeve component has sealing capability to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through the trocar sleeve during a surgical procedure

The ENDOPATH® OPTIVIEW™ Optical Surgical Obturator and Sleeve shall be provided in a variety of size sleeves from 3mm to 12mm in diameter and 65mm to 155mm in length.

The sleeve component of the device will be supplied with or without a stopcock for insufflation, with seals to maintain pneumoperitoneum as instruments are passed through the trocar sleeve, with or without a desufflation lever, and with or without stability threads for additional retention of the sleeve while it is in tissue.

Intended use

The intended use of the New Device is to establish a path of entry for minimally invasive instruments.

Continued on next page

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

Indications statement	The ENDOPATH® OPTIVIEW™ Optical Surgical Obturator and Sleeve has applications in abdominal, thoracic and gynecological minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The device utilizes an optical element to visualize tissue layers during insertion. The obturator can be used without visualization for primary and secondary insertions.
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 with or without visualization, 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	July 8, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 1 1997

Mr. Ivan S. Placko
Project Manager, Regulatory Affairs
Ethicon Endo-Surgery , Inc.
4545 Creek Road
Cincinnati, Ohio 45242-2839

Re: K972578
Trade Name: ENDOPATH® Optiview™ Optical Surgical Obturator and Sleeve
Regulatory Class: II
Product Code: GCJ
Dated: July 8, 1997
Received: July 10, 1997

Dear Mr. Placko:

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: K 972578
Device Name: ENDOPATH® OPTIVIEW™ Optical Surgical Obturator and Sleeve

Indications for Use:
The ENDOPATH® OPTIVIEW™ Optical Surgical Obturator and Sleeve has applications in abdominal, thoracic and gynecological minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The obturator can be used without visualization for primary and secondary insertions.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 972578