

4/1/99



ETHICON ENDO-SURGERY, INC.

a Johnson & Johnson company

4545 CREEK ROAD  
CINCINNATI, OH 45242-2839

K990028

## Appendix A - 510(k) Summary of Safety and Effectiveness

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|---------------|--|
| <b>Device</b> | <ul style="list-style-type: none"> <li>• Trade Name/Proprietary Name: ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve</li> <li>• Classification Name: Endoscope and Accessories</li> <li>• Common Name: Surgical Trocar</li> </ul> |
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<b>Legally marketed device</b>	ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve manufactured by Ethicon Endo-Surgery, Inc.
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<b>Device description</b>	The ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve consists of an obturator and a 5mm, 11mm, or 12mm sleeve.
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The clear, tapered optical element, when used with an endoscope, provides visibility of individual tissue layers during insertion. The blunt tip may reduce risk of trauma to abdominal viscera. An insufflation adapter, when supplied, is compatible with standard luer lock fittings and provides for insufflation of the abdominal cavity. The ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve has a sealing range that accommodates appropriately sized instruments. The obturator accommodates an appropriately sized zero degree endoscope. There are two obturator ergonomic options:

- **O** designated codes without a handle, and
- **H** designated codes with an integral pistol grip handle which aids in the insertion of the device.

*Continued on next page*

## 510(k) Summary of Safety and Effectiveness, Continued

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<b>Intended use</b>	The intended use of the ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve is to establish a path of entry for endoscopic instruments.
<b>Indications for use</b>	The ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve has applications in abdominal, gynecologic, and thoracic minimally invasive surgical procedures as well as endoscopic surgery of superficial veins and fascia of the lower extremities to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments. The trocar may be used without visualization for primary and secondary insertions.
<b>Technological characteristics</b>	The technological characteristics of the subject device are the same as the predicate device.
<b>Performance data</b>	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. These 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.
<b>Conclusion</b>	Based on the 510(k) summaries and 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.
<b>Contact</b>	Chuck Tabri, Regulatory Affairs Associate Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242 Telephone (513) 483-3532 Fax (513) 786-7134
<b>Date</b>	December 31, 1998



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 1 1999

Mr. Chuck Tabri  
Regulatory Affairs Associate  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242

Re: K990028  
Trade Name: ENDOPATH® OPTIVIEW® Optical Surgical Obturator and Sleeve  
Regulatory Class: II  
Product Code: GCJ  
Dated: December 31, 1998  
Received: January 5, 1999

Dear Mr. Tabri:

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.

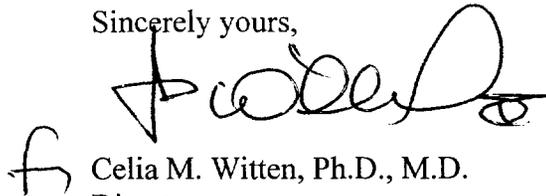
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Chuck Tabri

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

f 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

510(k) NUMBER (IF KNOWN): K990028

DEVICE NAME: ENDOPATH\* OPTIVIEW\* Optical Surgical Obturator and Sleeve

INDICATIONS FOR USE:

The ENDOPATH\* OPTIVIEW\* Optical Surgical Obturator and Sleeve has applications in abdominal, gynecologic, and thoracic minimally invasive surgical procedures as well as endoscopic surgery of superficial veins and fascia of the lower extremities to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments. The trocar may be used without visualization for primary and secondary insertions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter-Use  
(Optional Format 1)

[Signature]  
(Division Sign-Off)  
Division of General Restorative Devices K990028  
510(k) Number K990028