FEB 3 1999

K983925

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® Ultra Veress Insufflation Needle is a spring-loaded, blunt stylet safety mechanism similar in function to a Veress needle. It is used to establish pneumoperitoneum prior to abdominal endoscopy. The 14 gauge stainless steel needle is attached at its proximal end to a plastic handle. The handle is shaped for comfort in the hand and contains a stopcock and a luer lock connector for insufflating the abdominal cavity. Inside the needle sleeve and extending beyond the needle tip is a spring-loaded, blunt stylet. The stylet retracts as the needle is pushed through the abdominal tissue and automatically advances forward once the peritoneum is established.
Intended use	The intended use of the New Device is the establishment of pneumonperitoneum.
Indications	The ENDOPATH® Ultra Veress Insufflation Needle has applications in gynecologic laparoscopy and other minimally invasive abdominal procedures for establishment of pneumonperitoneum.
Contra-indications	The instrument is not intended for use when minimally invasive techniques are contraindicated.

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	Bench data was 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 criteria evaluated are flow rate, spring force to deflect stylet, audible rate, and needle penetration. From the data generated, it can be concluded that the New Device performed equivalent 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	Edwin O. Billips, RAC Senior Associate Regulatory Affairs Ethicon Endo-Surgery, Inc. 4545 Creek Road Cincinnati, Ohio 45242
Date	November 2, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 1999

Edwin O. Billips, RAC
Senior Associate, Regulatory Affairs
ETHICON ENDO-SURGERY, INC.
4545 Creek Road
Cincinnati, OH 45242-2839

Re: K983925
ENDOPATH® Ultra Veress Insufflation Needle
Dated: November 2, 1998
Received: November 5, 1998
Regulatory Class: II
21 CFR 884.1730/Procode: 85 HIF

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 legally marketed predicate 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K983925

Device Name ENDOPATH® Ultra Veress Insufflation Needle

Indications for use The ENDOPATH® Ultra Veress Insufflation Needle has applications in gynecologic laparoscopy and other minimally invasive abdominal procedures for establishment of pneumoperitoneum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983925

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)