

AUG 7, 1997

K971738

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® Resposable Trocar System consists of three main components: a Single Use obturator, a Single Use trocar sleeve housing and a reusable trocar sleeve.

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 reduce the likelihood of injury to internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered.

The trocar sleeve housing has an inner and outer seal to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through the cannula during a surgical procedure. Some trocar sleeve housings are provided with a stopcock for insufflating the operative space. Integral threads along the outside diameter of the cannula portion of the trocar sleeve provide a retention mechanism to stabilize the trocar sleeve in tissue.

The reusable trocar sleeve, supplied smooth or threaded, is manufactured so that it may be cleaned, sterilized, and reused.

The ENDOPATH® Resposable Trocar System shall be provided in a variety of sizes from 5mm to 12mm in diameter and 50mm to 150mm in length. In addition to the size variety they are supplied with or without stopcock for insufflation.

Intended use

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

Indications statement

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

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 Devices.
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 Devices in mating the obturator with the sleeve, insertion into the operative cavity, shield action to cover blade, 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 Devices 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	May 9, 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG -7 1997

Re: K971738
Trade Name: ENDOPATH® Resposable Trocar System
Regulatory Class: II
Product Code: GCJ
Dated: May 9, 1997
Received: May 12, 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.

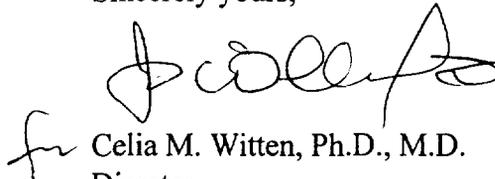
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



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

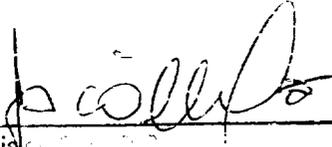
Following is the Indications for Use Statement:

510(k) Number: K 971738
Device Name: ENDOPATH® Trocar

Indications for Use:

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

Prescription Use X
(Per 21 CFR 801.109)



(Division of) _____
Division of _____ Devices
510(k) Number K 971738