K020428

ENDOPATH® Dilating Tip Trocar
510(k) Summary of Safety and Effectiveness

MAR 4 2002

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Elizabeth Miller
Regulatory Affairs Specialist

Date Prepared:
February 21, 2002

Name of Device
Trade Name: ENDOPATH® Dilating Tip Trocar
Classification Name: Laparoscope, General & Plastic Surgery

Predicate Device: ENDOPATH® Dilating Tip Trocar
ENDOPATH® Non-Bladed Obturator and Sleeve

Device Description: The ENDOPATH® Dilating Tip Trocar in sizes ranging from 5mm to 12mm in diameter is a sterile, single patient use instrument consisting of a sharp flat bladed tip and a spring-loaded shield. The shield is designed to cover the flat bladed tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered.

The trocar sleeve contains an outer gasket and internal flapper valve with a seal to minimize gas leakage when instruments are inserted or withdrawn. The size of the trocar corresponds to the maximum size of the instrument that can be used in that trocar. There is a stopcock valve for gas insufflation and a desufflation lever for gas evacuation.

Intended Use: The ENDOPATH® Dilating Tip Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments..

Technological Characteristics: The technological characteristics of the new device are the same as those of the predicate device with the exception of the sleeve/housing. The material is the characteristic that differs from the predicate device to the new.

Performance Data: Bench testing was performed to ensure that the device performs as intended. All testing demonstrated satisfactory performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Ethicon Endo-Surgery, Inc.
Elizabeth Miller
Regulatory Affairs Specialist
4545 Creek Road
Cincinnati, Ohio 45242

Re: K020428
Trade Name: Endopath® Dilating Rip Trocar
Regulation Number: 876.1500
Regulation Name: Laparoscope, General and Plastic Surgery
Regulatory Class: II
Product Code: GCJ
Dated: February 7, 2002
Received: February 8, 2002

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020428

Device Name: ENDOPATH® Dilating Tip Trocar

Indications for Use:

The ENDOPATH® Dilating Tip Trocar has application in thoracic, gynecologic laparoscopy, and other abdominal procedures to establish a path of entry for endoscopic instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020428