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K032676 1/2



# ENDOPATH® III Trocar System
# 510(k) Summary of Safety and Effectiveness

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

**Contact**
Elizabeth Miller
Regulatory Affairs Associate I

**Date Prepared:**
August 28, 2003

**Name of Device**
Trade Name: ENDOPATH® III Bladeless Trocars
ENDOPATH® III Blunt Tip Trocars
ENDOPATH® III Dilating Tip Trocars
Classification Name: Laparoscope, General & Plastic Surgery

**Predicate Device:** ENDOPATH® Dilating Tip Trocar
ENDOPATH® Non-Bladed Obturator and Sleeve
ENDOPATH® Bladeless Trocar
ENDOPATH® Blunt Tip Trocar
ENDOPATH® OneSeal Reducer Cap
ENDOPATH® TRISTAR™ Low Profile Trocars with Threaded Sleeve

**Device Description:** The ENDOPATH® III Trocars are sterile single patient use instruments consisting of a radiolucent sleeve and obturator in sizes ranging from 5-12 mm in diameter. There are three different obturators Bladeless, Blunt Tip and Dilating Tip. The Bladeless obturator contains a clear, tapered optical element, which when used with an endoscope, provides visibility of individual tissue layers during insertion. The Bladeless obturator accommodates an appropriately sized zero endoscope. The Blunt Tip obturator has a blunt plastic tip, which gently moves aside any internal viscera that may be adjacent to the abdominal or thoracic wall. The Dilating Tip obturator has a sharp flat-bladed tip and a spring-loaded shield. The shield on the Dilating Tip obturator 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 two seals, an outer integrated removable self-adjusting seal to accommodate instruments ranging from 5mm to 12mm in diameter where indicated and an internal seal. Together, these seals minimize gas leakage when instruments are

inserted or withdrawn through the trocar. The 5mm trocar sleeve does not contain an integrated removable seal and accommodates only 5mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in closed position when it is parallel to the sleeve.

**Intended Use:** The ENDOPATH® III Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

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

The ENDOPATH® III Blunt Tip Trocar has applications in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments.

**Technological Characteristics:** The technological characteristics of the new device are different in that the new trocar has two seals a universal removable seal and an internal duckbill seal made of polyisoprene. A latch has been added for the removal and locking of the universal seal. The design of the obturator cannula and trocar sleeve housing has been changed to incorporate a low profile design for ergonomic consideration.

**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

OCT 3 0 2003

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

Re: K032676
Trade/Device Name: ENDOPATH® III Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 28, 2003
Received: August 29, 2003

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

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): _____

Device Name: ENDOPATH® III Trocar System

Indications for Use:

The ENDOPATH® III Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

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

The ENDOPATH® III Blunt Tip Trocar has applications in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032676

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)