K062209

510(k) Summary

Company Ethicon Endo-Surgery, LLC
Angora Industrial Park, Building G
Caguas, Puerto Rico 00725

OCT 10 2006

Contact Dennis Hahn
Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
Phone: (513) 337-3134
FAX: (513) 337-1444
Email: dhahn1@eesus.jnj.com

Date Prepared July 31, 2006

Device Name Trade Name: BASX™ Bladeless Trocar
Common or Usual Name: Surgical Trocar
Classification Name: Laparoscope, General & Plastic Surgery

Predicate Devices ENDOPATH® Optiview Optical Surgical Obturator and Sleeve
ENDOPATH® Non-Bladed Solid Obturator (with Sleeve)
ENDOPTH® XCEL™ Bladeless Trocar

Device Description: The BASX™ Bladeless Trocar is a sterile single patient use instrument consisting of a radiolucent sleeve in sizes 5mm, 11mm, and 12 mm diameters. The trocar sleeve for the 11 and 12mm devices contains two seals, an outer integrated self-adjusting seal that accommodates instruments ranging from 5mm to 12mm in diameter where indicated and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5mm trocar sleeve accommodates only 5mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation.

Indications for Use: The BASX™ Bladeless Trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

Contraindications: This device is not intended for thoracic applications or when minimally invasive techniques are contraindicated.

Technological Characteristics: The BASX™ Bladeless Trocar consists of a sleeve and housing with welded a stopcock assembly and an integrated two seal system for maintaining pneumoperitoneum. The sleeve cannula contains integrated stability threads for abdominal wall retention. The obturator is a one-piece molded design. The trocar uses materials that are similar to those used in the predicate devices.

Performance Data Bench testing evaluation was performed to demonstrate that the new device performs as intended. Design and development were predicated on use of technology currently used in Ethicon Endo-Surgery trocar devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2006

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Mr. Dennis Hahn
Director, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K062209
Trade/Device Name: BASX™ Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 31, 2006
Received: August 1, 2006

Dear Mr. Hahn:

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.

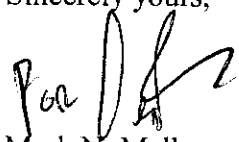
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062209

Device Name: BASX™ Bladeless Trocar

Indications for Use:

The BASX™ Bladeless Trocar has applications in abdominal and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062209