510(k) Summary

OCT 1 2012

Company
Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact
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Date Prepared: August 15, 2012

Device Name
Trade Name: ENDOPATH® XCEL® Trocar with OPTIVIEW™ Technology
Common Name: Trocar

Classification Names Laparoscope, General & Plastic Surgery
Regulation Number 876.1500

Predicate Device
ENDOPATH® XCEL® 12mm Trocars, submitted as ENDOPATH® III Trocar System, K032676

Device Description:

The ENDOPATH® XCEL® Trocars with OPTIVIEW™ Technology are sterile, single-patient use endoscopic devices used to create an access port to the inside of the body cavity to perform endoscopic surgery. The trocars accommodate instruments ranging from 5 to 12 mm diameter. The trocars contain two seals, an outer integrated removable self-adjusting seal and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation. The trocars contain OPTIVIEW™ Technology, a design enhancement that reduces the incidence of trocar-induced endoscope lens smudging during endoscope insertion. Endoscope smudging occurs when bodily fluids and debris smear across the endoscope lens during a laparoscopic procedure. Trocar-induced smudging occurs when these bodily fluids and debris are deposited within the trocar's seal system when an endoscope or instrument has been exchanged through the trocar.

Indication for Use:

The ENDOPATH® XCEL® Bladeless Trocar with OPTIVIEW™ Technology has applications in abdominal, thoracic, and gynecologic minimally invasive surgical

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® XCEL® Blunt Tip Trocar with OPTIVIEW™ Technology has application in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments.

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

The ENDOPATH® XCEL® Universal Trocar Stability Sleeve with OPTIVIEW™ Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Technological Characteristics:

ENDOPATH® XCEL® Trocars with OPTIVIEW™ Technology have similar design, dimensions, and features as the predicate devices. The devices consist of two components: a sleeve and an obturator. The sleeve and obturator are used to create the access port. The obturator is a subsystem used to assist in the process of installing the sleeve port through the body tissue. After installation, the obturator is not required for trocar performance. The Bladeless Trocar obturators accommodate an appropriately sized 0° endoscope and provide visibility of individual tissue layers during insertion.

The sleeve has an integrated two-seal system for maintaining pneumoperitoneum. The trocar sleeves contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 to 12 mm in diameter and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted through or completely withdrawn from the trocar. The sleeve has a welded stopcock assembly, which is compatible with standard luer lock fittings, and provides attachment for gas insufflation and desufflation of the pneumoperitoneum. The sleeve cannula contains integrated stability threads for abdominal wall retention. The ENDOPATH® XCEL® Trocars with OPTIVIEW™ Technology are equivalent to the predicate devices' indications and performance.

Performance Data: Bench testing was performed to demonstrate that the device performs as intended and is substantially equivalent to the predicate device, ENDOPATH® XCEL® Trocars. To validate that the subject device performs as intended, the following bench testing was performed:

- Drag Force of an Instrument within the Trocar, Peak Force
- Drag Force of an Instrument within the Trocar, Average Force
- Trocar Seal System Durability, demonstrated by Air Leak Performance
- Air Leak Performance While Trocar is Under Torque
- Endoscope Visualization Image Quality
- Ergonomic Force to Attach and Detach Universal Seal Cap

Please note that animal testing was not used to verify substantial equivalence of the ENDOPATH® XCEL® Trocars with OPTIVIEW™ Technology to the predicate device ENDOPATH® XCEL® Trocars.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Enthicon End-Surgery, LLC
% Enthicon End-Surgery, Incorporated
Ms. Emily Kruetzkamp
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

OCT 1 2012

Re: K122511
Trade/Device Name: ENDOPATH® XCEL® Bladeless Trocar with OPTIVIEW™ Technology
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 15, 2012
Received: August 17, 2012

Dear Ms. Kruetzkamp:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K122511

Indications for Use Form

Indications for Use

510(k) Number (if known): K122511

Device Name: ENDOPATH® XCEL® Bladeless Trocar with OPTIVIEW™ Technology

Indications for Use:

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

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)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122511

Indications for Use Form

Indications for Use

510(k) Number (if known): K 122511

Device Name ENDOPATH® XCEL® Blunt Tip Trocar with OPTIVIEW™ Technology

Indications for Use:

The ENDOPATH® XCEL® Blunt Tip Trocar has application in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive 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)

Neil R. P. Ogden for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122511

Indications for Use Form

Indications for Use

510(k) Number (if known): K 122511

Device Name: ENDOPATH® XCEL® Dilating Tip Trocar with OPTIVIEW™ Technology

Indications for Use:

The ENDOPATH® XCEL® Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal 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)

Neil R. Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122511

Indications for Use Form

Indications for Use

510(k) Number (if known): K122511

Device Name: ENDOPATH® XCEL® Universal Trocar Stability Sleeve with OPTIVIEW™ Technology

Indications for Use:

The ENDOPATH® XCEL® Universal Trocar Stability Sleeve has applications in thoracic, gynecologic laparoscopy and other abdominal 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)

Mark RPDyden for mxm

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122511