K112349

SEP - 1 2011

Versaport™ V2 Bladeless Optical Trocar System

## 510(k) Summary of Safety and Effectiveness

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|---|---|
| SUBMITTER: | Covidien<br>60 Middletown Avenue<br>North Haven, CT 06473 USA |
| CONTACT PERSON: | Angela Van Arsdale<br>Product Specialist, Regulatory Affairs |
| DATE PREPARED: | August 10, 2011 |
| TRADE/PROPRIETARY NAME: | Versaport™ V2 Bladeless Optical Trocar or Versaport™ Bladeless Optical |
| COMMON/USUAL NAME: | Surgical Trocar |
| CLASSIFICATION NAME: | Endoscope and Accessories |
| PREDICATE DEVICE(S): | Versaport™ Bladeless Low ProfileTrocar [K100548]<br><br>Endopath® Xcel™ Trocar [K011257] |
| DEVICE DESCRIPTION: | The Versaport™ V2 bladeless optical trocar with a low profile design and transparent fixation cannula is available in 5 mm standard (100mm), 5 mm short (70mm) and 5mm long (150mm) cannula lengths. The Versaport™ V2 bladeless optical 5mm trocar with transparent fixation cannula and obturator allows optical entry for visualization of tissue layers during insertion. The obturator housing contains a scope retention mechanism. The trocar housing contains internal seals to prevent loss of pneumoperitoneum when instruments are inserted into a port or withdrawn completely from a port. The 5 mm Versaport™ seal system accommodates 5mm instruments respectively. There is a luer lock with cap for insufflation and rapid desufflation. |
| INTENDED USE: | The Versaport™ Bladeless Optical Trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions. |
| TECHNICAL CHARACTERISTICS: | The subject device (Versaport™ V2 Bladeless Optical Trocar) has similar design, lengths, and optical features as the predicate devices. The design modifications includes a cannula material change, a bladeless obturator with a transparent optical window at the distal end, an obturator housing scope retention mechanism and external interlocking snaps. The scope retention mechanism is located within the obturator housing allowing for secured insertion and retention of an appropriately sized 0° laparoscope for visualization of tissue layers during insertion into the body cavity. The external interlocking snaps secure the obturator to the cannula. The Versaport™ Bladeless V2 Optical trocar is equivalent to the predicate devices in terms of its intended use and fundamental technology. |
| MATERIALS: | All components of the Versaport™ Bladeless Optical Trocar are comprised of materials which were tested in accordance with ISO Standard 10993-1. |

PERFORMANCE DATA:

In-vitro and in-vivo tests were performed to verify that the performance of the Versaport™ V2 Bladeless Optical 5mm trocar is substantially equivalent to the predicate device, Endopath® Xcel trocar [K011257], To validate that the subject device performs as intended to facilitate endoscopic access into the body cavity, the following describes the testing performed:

- In Vitro Leak Resistance
- In Vitro and In Vivo Penetration and Fixation Forces
- In Vitro and In Vivo Fixation Force
- In Vitro and In Vivo Insertion and Removal Forces
- In Vitro Snap Feature Retention Force
- In Vitro One-Handed Use
- In Vitro Scope Insertion and Retention Forces
- In Vivo Multiple Penetration Forces
- In Vivo Visualization of Tissue Layers

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

Covidien
% Ms. Angela Van Arsdale
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

SEP - 1 2011

Re: K112349
Trade/Device Name: Versaport™ V2 Bladeless Optical Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 15, 2011
Received: August 16, 2011

Dear Ms. Arsdale:

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

# Indications for Use

510(k) Number (if known): K112349

Device Name:

**Versaport™ V2 Bladeless Optical Trocar**

Indications for Use:

The Versaport™ Bladeless Optical Trocar is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

Prescription Use __X__ (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 IF 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 K112349