510(k) Summary of Safety and Effectiveness

MAR 1 4 2013

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Sarah Rizk Senior Product Specialist, Regulatory Affairs
DATE PREPARED:	February 21, 2013
TRADE/PROPRIETARY NAME:	Versaport™ V2 Bladeless Optical Trocar
COMMON/USUAL NAME:	Optical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories
PREDICATE DEVICE(S):	Versaport™ V2 Bladeless Optical Trocar [K112349] Versaport™ Bladeless Trocar [K081169]
DEVICE DESCRIPTION:	The Versaport™ V2 Bladeless Optical Trocar 11mm and 12mm with a transparent cannula is available in standard (100mm), short (70mm) and long (150mm) cannula lengths. The Versaport™ V2 Bladeless Optical Trocar with transparent 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trocar housing contains internal seals to prevent loss of pneumoperitoneum when instruments are inserted into a port or withdrawn completely from a port.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 11mm and 12mm Versaport™ seal system accommodate instruments indicated as 5mm up to 11mm and 12mm respectively. These features are the same as the Versaport™ V2 Bladeless Optical Trocar (5mm) [K112349].
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 proposed device (Versaport™ V2 Bladeless Optical Trocar, 11mm and 12mm) has similar design, lengths, and optical features as the predicate devices. The Versaport™ V2 Bladeless Optical Trocar, 11mm and 12mm, includes a transparent cannula, 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. There is a 3 way stopcock for insufflation and rapid desufflation. 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 11mm and 12mm 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 11mm and 12mm trocars are substantially equivalent to the predicate devices. To validate that the proposed device performs as intended to facilitate endoscopic access into the body cavity, the following describes the testing performed:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 14, 2013

Covidien, Formerly US Surgical a Division of Tyco Healthcare
% Ms. Sarah Rizk
Senior Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K130435
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: February 21, 2013
Received: February 21, 2013

Dear Ms. Rizk:

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,

FOR

Peter D. Rumm -S

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

Enclosure

Versaport™ V2 Bladeless Optical Trocar System

Indications for Use

510(k) Number (if known): K130435

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 AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (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)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.03.14 06:42:01 -04'00' for

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130435