DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 8, 2017

Covidien LLC
Mr. Gary LeMere
Sr. Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K163654
Trade/Device Name: VersaOne Fascial Closure System Bladed Trocar, VersaOne Fascial Closure System Bladeless Trocar, VersaOne Fascial Closure System Optical Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 1, 2017
Received: March 3, 2017

Dear Mr. LeMere:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163654

Device Name

VersaOne™ Fascial Closure System Bladed Trocar,
VersaOne™ Fascial Closure System Bladeless Trocar,
VersaOne™ Fascial Closure System Optical Trocar

Indications for Use *(Describe)*

The VersaOne™ Fascial Closure System Bladed Trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

The VersaOne™ Fascial Closure System Bladeless Trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

The VersaOne™ Fascial Closure System Optical Trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510(k) Summary

SUBMITTER: Covidien llc
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DATE PREPARED: December 20, 2016

PRODUCT CODE: GCJ

REGULATION NUMBER: 21 CFR 876.1500

REVIEW PANEL: Gastroenterology-urology devices

TRADE/PROPRIETARY NAME: VersaOne™ Fascial Closure System Bladed Trocar
VersaOne™ Fascial Closure System Bladeless Trocar
VersaOne™ Fascial Closure System Optical Trocar

COMMON/USUAL NAME: Surgical Trocar

CLASSIFICATION NAME: Endoscope and Accessories

PREDICATE DEVICES: (K151548) - VersaOne™ Bladed Trocar 12mm, VersaOne™ Bladeless Trocar 12mm
(K130435) - Special 510(k) for Versaport™ V2 Bladeless Optical trocar

REFERENCE DEVICE: (K980123) - Carter-Thomason Needle-Point Suture Passer Instrument Set [Carter-Thomason CloseSure System]

DEVICE DESCRIPTION:

The VersaOne™ Fascial Closure System Bladed Trocar (12mm) is available in standard length (100mm) transparent cannula. The Bladed Trocar obturator has a dolphin nose (conical) shaped tip with a sharp linear blade and a spring-loaded locking shield. The blade is used to cut the tissues as the trocar is inserted into the body cavity. The shield advances to cover the blade upon entry into a free space. The cannula assembly is composed of a seal system, trocar housing, transparent cannula sleeve, and a stopcock. 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 cannula seal system accommodates instruments ranging 5mm up to 12mm. The distal end of the trocar cannula has two windows, 180 degrees apart, covered by a pierce-able

membrane. A guide is provided which fits inside the trocar cannula to guide a suture passer through the wall of the cannula and soft tissue to be approximated. The stopcock valve is for insufflation and desufflation. A reusable suture passer is provided, which delivers suture through the trocar cannula to aid in port site closure.

The VersaOne™ Fascial Closure System Bladeless Trocar (12mm) is available in standard length (100mm) transparent cannula. Bladeless Trocar obturator has a dolphin nose (conical) shaped bladeless tip. The conical shape is for smooth insertion into the body cavity by spreading the tissue layers during insertion. The cannula assembly is composed of a seal system, trocar housing, transparent cannula sleeve, and a stopcock. 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 cannula seal system accommodates instruments ranging 5mm up to 12mm. The distal end of the trocar cannula has two windows, 180 degrees apart, covered by a pierce-able membrane. A guide is provided which fits inside the trocar cannula to guide a suture passer through the wall of the cannula and soft tissue to be approximated. The stopcock valve is for insufflation and desufflation. A reusable suture passer is provided, which delivers suture through the trocar cannula to aid in port site closure.

The VersaOne™ Fascial Closure System Optical Trocar (12mm) is available in standard length (100mm) transparent cannula. The Optical Trocar with transparent cannula and obturator allows for visualization of tissue layers during insertion. The obturator housing contains a scope retention mechanism. The cannula assembly is composed of a seal system, trocar housing, transparent cannula sleeve, and a stopcock. 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 cannula seal system accommodates instruments ranging 5mm up to 12mm. The distal end of the trocar cannula has two windows, 180 degrees apart, covered by a pierce-able membrane. A guide is provided which fits inside the trocar cannula to guide a suture passer through the wall of the cannula and soft tissue to be approximated. The stopcock valve is for insufflation and desufflation. A reusable suture passer is provided, which delivers suture through the trocar cannula to aid in port site closure.

INTENDED USE:
The VersaOne™ Fascial Closure System Bladed Trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

The VersaOne™ Fascial Closure System Bladeless trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

The VersaOne™ Fascial Closure System Optical Trocar with fixation cannula is intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The VersaOne™ Fascial Closure System combines the existing technologies of the Covidien's VersaOne™ Bladed and Bladeless and Versaport Bladeless Optical Trocar systems with manual port site closure using a guide and suture passer. The VersaOne™

Fascial Closure System is available in three different models (reorder codes) each differing only by the obturator supplied; Bladed, Bladeless or Optical. The suture passer is a universal component to all three models. Below is a summary of characteristics for each of the three models.

Proposed Device	Predicate Device	Similarities	Differences
VersaOne™ Fascial Closure System Bladed Trocar	K151548 VersaOne™ Bladed Trocar 12mm	Trocar Cannula maintains a port of entry for laparoscopic instruments. Both use the exact same bladed obturator Both use the same self-adjusting seal housing Both are single use, EtO sterilized Both have three main components: trocar cannula, seal housing and a bladed obturator	The VersaOne™ Fascial Closure System Bladed Trocar cannula has two windows near the distal end to allow the suture passer to exit. The predicate VersaOne™ Bladed Trocar does not have any openings along the trocar cannula The VersaOne™ Fascial Closure System Bladed Trocar cannula has a line and arrow printed on the side of the cannula for tissue alignment. The predicate VersaOne™ Bladed Trocar 12mm has no printing on the trocar cannula The predicate VersaOne™ Bladed Trocar 12mm has application in gynecologic, general, thoracic and urologic procedures. The VersaOne™ Fascial Closure System Bladed Trocar has the same applications with the exception of thoracic. With the addition of two new features, the VersaOne™ Fascial Closure System Bladed Trocar cannula also serves to facilitate closure of the port site. A guide that is inserted into the cannula provides a pathway for the suture passer to deliver suture into the body cavity. The predicate trocar does not have this feature. This feature is similar to the Reference Device (K980123).

Proposed Device	Predicate Device	Similarities	Differences
VersaOne™ Fascial Closure System Bladeless Trocar	K151548 VersaOne™ Bladeless Trocar 12mm	Trocar Cannula maintains a port of entry for laparoscopic instruments. Both use the exact same bladeless obturator Both use the same self-adjusting seal housing Both are single use, EtO sterilized Both have three main components: trocar cannula, seal housing and a bladeless obturator	The VersaOne™ Fascial Closure System Bladeless Trocar cannula has two windows near the distal end to allow the suture passer to exit. The predicate VersaOne™ Bladeless Trocar does not have any openings along the trocar cannula The VersaOne™ Fascial Closure System Bladeless Trocar cannula has a line and arrow printed on the side of the cannula for tissue alignment. The predicate VersaOne™ Bladed Trocar 12mm has no printing on the trocar cannula The predicate VersaOne™ Bladeless Trocar 12mm has application in gynecologic, general, thoracic and urologic procedures. The VersaOne™ Fascial Closure System Bladeless Trocar has the same applications with the exception of thoracic. With the addition of two new features, the VersaOne™ Fascial Closure System Bladeless Trocar cannula also serves to facilitate closure of the port site. A guide that is inserted into the cannula provides a pathway for the suture passer to deliver suture into the body cavity. The predicate trocar does not have this feature. This feature is similar to the Reference Device (K980123).

Proposed Device	Predicate Device	Similarities	Differences
VersaOne™ Fascial Closure System Optical Trocar	K130435 Versaport™ V2 Bladeless Optical trocar	Trocar Cannula maintains a port of entry for laparoscopic instruments. Both use the exact same (bladeless) optical obturator Both use the same self-adjusting seal housing Both are single use, EtO sterilized Both have three main components: trocar cannula, seal housing and an optical obturator	The VersaOne™ Fascial Closure System Optical Trocar cannula has two windows near the distal end to allow the suture passer to exit. The predicate Versaport V2 Bladeless Optical Trocar does not have any openings along the trocar cannula The VersaOne™ Fascial Closure System Optical Trocar cannula has a line and arrow printed on the side of the cannula for tissue alignment. The predicate Versaport™ V2 Bladeless Optical Trocar 12mm has no printing on the trocar cannula The predicate VersaOne™ Bladeless Optical Trocar 12mm has application in gynecologic, general, thoracic and urologic procedures. The VersaOne™ Fascial Closure System Optical Trocar has the same applications with the exception of thoracic. With the addition of two new features, the VersaOne™ Fascial Closure System Optical Trocar cannula also serves to facilitate closure of the port site. A guide that is inserted into the cannula provides a pathway for the suture passer to deliver suture into the body cavity. The predicate trocar does not have this feature. This feature is similar to the Reference Device (K980123).

COMPATIBILITY DATA:
Biocompatibility testing was completed in accordance International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation Dated June 6, 2016 and Testing within a Risk Management Process” as recognized by FDA and FDA Guidance for Industry: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process dated March 17, 2015.

The following tests were conducted, which are appropriate to the patient contact profile of the proposed devices:

- Cytotoxicity
- Sensitization
- Intracutaneous irritation
- Pyrogenicity

STERILIZATION:
Sterilization studies were completed for single use devices sterilized by ethylene oxide in accordance with ISO 11135-1 *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical device*s and ISO 10993-7 *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals* as recognized by FDA

CLEANING AND STERILIZATION:
Cleaning and sterilization studies were completed for the reusable suture passer in accordance with *Guidance for Industry and Food and Drug Administration Staff; Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* dated March 17, 2015 and AAMI TIR30 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices* and AAMI TIR12 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* as recognized by FDA

PERFORMANCE DATA:
Performance studies were conducted to demonstrate the proposed device(s), VersaOne™ Fascial Closure System trocars are substantially equivalent to the predicate devices. In-vitro (bench), in-vivo (live animal) and comparison testing to predicate support the intended use of this device and are as follows:

<u>VersaOne™ Fascial Closure System In-Vitro (bench) Testing:</u>

- Visual Examination
- Suture Passer Puncture Force
- Suture Passer handle open force
- Guide insertion force
- Guide torque to lock
- Suture Passer, suture Retention force
- Trocar Cannula Leak Test
- Cannula Leak test with guide
- Trocar Cannula Fixation Force

<u>VersaOne™ Fascial Closure System In-Vivo (live animal) Testing:</u>

- Trocar penetration force
- Trocar fixation force
- Functional Test

RELIABILITY TESTING:
Accelerated life cycle testing was performed for the proposed VersaOne™ Fascial Closure System Reusable Suture Passer.

HUMAN FACTORS:

Human Factors evaluations were completed using
IEC 62366-1 Medical Devices - Part 1: Application of Usability Engineering to Medical Devices and FDA guidance Applying Human Factors and Usability Engineering to Medical Devices Dated February 3, 2016. While submission of Human Factors evaluation is not a requirement for premarket submission, a summative usability report is included as part of the objective evidence demonstrating safety and effectiveness.

CONCLUSION:
Supporting data enclosed in this submission demonstrates that the proposed VersaOne™ Fascial Closure System Bladed Trocar, VersaOne™ Fascial Closure System Bladeless Trocar and VersaOne™ Fascial Closure System Optical Trocar devices are as safe, as effective, and performs as well as, or better than their predicate devices and do not present any new issues of safety or effectiveness.