August 26, 2020

Covidien
Stephanie Wilde
Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K201805
Trade/Device Name: VersaOne™ Reusable Positioning Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 30, 2020
Received: July 1, 2020

Dear Stephanie Wilde:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201805

Device Name
VersaOne™ Reusable Positioning Trocar System

Indications for Use *(Describe)*
The VersaOne™ reusable positioning trocar system is intended for use in a variety of gynecologic, general, thoracic and urological endoscopic procedures to create and maintain a port of entry. The 11mm and 12 mm trocar may be used with or without visualization for primary and secondary insertions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary

Submitter

Company	Covidien 60 Middletown Avenue North Haven, CT 06473
Contact Person	Stephanie Wilde Regulatory Affairs Specialist Tel: (203) 492-5590 Cell: (475) 331-0244 Email: Stephanie.wilde@medtronic.com
Date Prepared	24 August 2020

Device

Trade/Proprietary Name	VersaOne™ Reusable Positioning Trocar System
Common Name	Surgical Trocar
Classification Name	Endoscope and Accessories
Regulatory Class	II
Product Code	GCJ

Predicate Devices

Primary	K130435 – Versaport™ V2 Bladeless Optical Trocar
Secondary	K162584 – VersaOne™ Bladeless Trocar
Reference Device	K963115 – Versaport™ RT Trocar System

Device Description

The VersaOne™ Reusable Positioning Trocar System is available in 8mm bladeless and 11mm and 12mm optical configurations. Each configuration is available in standard (100mm) and long (150mm) trocar lengths. The VersaOne™ Reusable Positioning Trocar System is a four-component trocar, consisting of a reusable positioning cannula – which includes the cannula and cap, a single patient use seal, and a single patient use obturator. Each trocar size is suitable for use with instruments ranging from 5 mm up to the diameter of the cannula and cap. The 8mm bladeless obturator has a dolphin nose (conical) shaped bladeless tip and rounded doorknob obturator cap. The 11mm and 12mm optical obturator have a dolphin nose (conical) shaped bladeless tip with a transparent window at the distal end. The transparent window at the distal end of the obturator allows for optical entry for visualization of tissue layers during insertion. The optical obturator housing contains a scope retention mechanism. The cannula seal is a stand-alone component, self-adjusting for 5mm-12mm instruments. The seal assembly prevents a loss of pneumoperitoneum and includes a 3-way stopcock for insufflation and desufflation. The smooth titanium cannula sleeve has a bevel shape at the distal end to reduce penetration forces during insertion and laser marked graphics intended for future compatibility with Covidien/ Medtronic products. The seal and obturators are supplied sterile (sterilized via Ethylene Oxide (EtO) sterilization method) single use, whereas the cannula (cannula and cap) is supplied non-sterile and require sterilization by the user. All components are packaged individually.

Indications for Use

The VersaOne™ reusable positioning trocar system is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The 11mm and 12mm trocar may be used with or without visualization for primary and secondary insertions.

Comparison of Technological Characteristics with The Predicate Device

Creating and maintaining a port of entry during endoscopic procedures is the technological principle for both the proposed and predicate devices. The following table provides a summary comparison of the technological characteristics between the proposed device and predicate devices. The differences in technological characteristics do not raise new questions of safety and effectiveness.

Feature	**Proposed Device** VersaOne™ Reusable Positioning Trocar System	**Primary Predicate** K130435 – Versaport™ V2 Bladeless Optical Trocar	**Secondary Predicate** K162584 – VersaOne™ Bladeless Trocar
Indications for Use	The VersaOne™ reusable positioning trocar system is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry. The 11 mm and 12 mm trocar may be used with or without visualization for primary and secondary insertions.	The Versaport™ Bladeless Optical trocars are 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.	The VersaOne™ bladeless trocars are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
Trocar Configuration	Positioning Cannula Assembly (Reusable) Seal (Single-Use) Bladeless Obturator (Single-Use) Optical Obturator (Single-Use)	Cannula with seal system (Single-Use) Optical Obturator (Single-Use)	Cannula with seal system (Single-Use) Bladeless Obturator (Single-Use)
Trocar Sizes	8mm, 11mm, 12mm	11mm and 12mm	8mm
Trocar Lengths	Standard, Long	Short, Standard, Long	Standard, Long
Seal System Configuration	Seal cover Seal assembly Seal snap Envelope seal 3-way stopcock Seal body	Seal cover Seal assembly Seal housing	Seal cover Seal assembly Seal housing
Instrument Compatibility	Accommodates instrument diameter sizes 5mm to 8mm, 5mm to 11mm, and 5mm to 12mm	Accommodates instruments diameter sizes 5mm to 11mm, and 5mm to 12mm	Accommodates instrument diameter sizes 5mm to 8mm
Cannula Assembly Configuration	Cap Cannula Body Cannula Sleeve	Seal system Specimen removal button Cannula housing 3-way stopcock Cannula sleeve	Seal system Specimen removal button Cannula housing 3-way stopcock Cannula sleeve
Cannula Sleeve	Titanium Smooth with laser marked graphics at the distal end	Transparent Fixation (Ribbed) Transparent Smooth	Transparent Fixation (Ribbed)
Obturator	8mm Bladeless 11mm Bladeless Optical 12mm Bladeless Optical	11mm Bladeless Optical 12mm Bladeless Optical	8mm Bladeless
Use Conditions	Single use, supplied sterile Reusable, supplied non-sterile	Single use, supplied sterile	Single use, supplied sterile
Sterilization (single use)	Ethylene oxide (EtO) cycle to a SAL of 10^{-6}	Ethylene oxide (EtO) cycle to a SAL of 10^{-6}	Ethylene oxide (EtO) cycle to a SAL of 10^{-6}
Reprocessing (reusable)	Manual or automated cleaning and autoclave	Predicate does not have reusable components	Predicate does not have reusable components
Shelf Life (single use)	5 years	5 years	5 years

Feature	**Proposed Device** VersaOne™ Reusable Positioning Trocar System	**Primary Predicate** K130435 – Versaport™ V2 Bladeless Optical Trocar	**Secondary Predicate** K162584 – VersaOne™ Bladeless Trocar
Reuse Life (reusable)	IFU provides the user with a method to ascertain whether the device has exceeded its use life	Predicate does not have reusable components	Predicate does not have reusable components
Biocompatibility	Materials used have been evaluated and tested per ISO 10993-1.	Materials used have been evaluated and tested per ISO 10993-1.	Materials used have been evaluated and tested per ISO 10993-1.

Performance Data
The following performance data were provided in support of the substantial equivalence determination

Cleaning and Sterilization
Sterilization studies were completed for the single use components (seal, bladeless obturator, and bladeless optical obturator) sterilized by ethylene oxide, ensuring sterilization of 10^{-6} and demonstrating compliance with applicable FDA guidance and international standards. Cleaning and sterilization studies completed for the reusable component (cannula and cap) of the system, also demonstrated compliance with applicable FDA guidance and standards.

Shelf Life/ Reliability
All components of the proposed device were assessed to confirm compliance with the design inputs throughout its intended life.

Biocompatibility
Biocompatibility testing was completed in accordance with applicable FDA guidance and international standards related to ISO 10993-1. The following tests were conducted, which are appropriate to the patient contact profile of the proposed devices:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Pyrogenicity
- Acute Systemic Toxicity
- Chemical Characterization

Performance Testing
Performance studies were conducted to demonstrate the proposed VersaOne™ Reusable Positioning Trocar System is substantially equivalent to the predicate devices.

Bench (in-vitro) Performance Testing:

- Visual Inspection
- Instrument Insertion and Removal Force
- Insertion and Removal Force using VersaOne™ Obturator
- Leak Rate
- Insufflation Rate
- Desufflation Rate
- In Vitro Penetration Force
- Snap Feature Engagement Strength
- Seal System Lock Torque Strength
- Obturator Snap Button Force
- Cannula Strength Test
- Cannula Cap Attachment Torque
- Cannula Cap Removal Torque
- Seal Assembly Insertion / Removal Force

Acute Animal (in-vivo) Performance Testing:

- In-Vivo Penetration Force Standard Incision

Human Factors/Usability

Human factors and usability evaluations were completed per applicable standard and guidance. A summative usability report is included as part of the objective evidence demonstrating safety and effectiveness.

Conclusion

The supporting data enclosed in this submission demonstrates that the proposed VersaOne™ Reusable Positioning Trocar System is substantially equivalent to the predicate devices and does not present any new issues of safety or effectiveness.