Covidien
Michael Mach
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

June 27, 2022

Re: K213818
Trade/Device Name: VersaOne Optical Trocar with Fixation Ballon Cannula, VersaOne Universal Fixation Balloon Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 29, 2022
Received: May 2, 2022

Dear Michael Mach:

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 and Part 809); 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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213818

Device Name
VersaOne™ optical trocar with fixation balloon cannula
VersaOne™ universal fixation balloon cannula

Indications for Use *(Describe)*
The VersaOne™ optical trocar with fixation balloon cannula is indicated for use in general, gynecologic, thoracic and urologic minimally invasive surgical procedures.

The intended purpose of the device is to create and maintain a port of entry. The 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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DATE PREPARED:

June 15, 2022

SUBMITTER:

Covidien
60 Middletown Avenue
North Haven, CT 06473 USA

CONTACT PERSON:

Michael Mach
Senior Regulatory Affairs Specialist
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IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	VersaOne™ optical trocar with fixation balloon cannula/ VersaOne™ universal fixation balloon cannula
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR §876.1500
Product Code:	GCJ
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Trocar

PREDICATE DEVICE:

Proprietary/Trade Name:	VersaPort™ V2 Bladeless Optical Trocar and/or VersaPort™ Bladeless Optical Trocar
510(k) Number:	K112349 (S.E. September 1, 2011)
Manufacturer:	Covidien llc
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR §876.1500
Product Code:	GCJ
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Trocar

REFERENCE DEVICE:

Proprietary/Trade Name:	Origin Blunt Tip Surgical Trocar
510(k) Number:	K924011 (S.E. July 9, 1993)
Manufacturer:	Origin Medsystems, Inc.
Classification Name:	Endoscope and Accessories
Regulations Number:	21 CFR §876.1500
Product Codes:	GCJ
Device Class:	Class II
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Trocar

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DEVICE DESCRIPTION:

VersaOne™ optical trocar with fixation balloon cannula with a low-profile design is a 5mm diameter transparent fixation cannula in various lengths and is comprised of three components: obturator with optical tip, seal system, and cannula assembly. The obturator is bladeless and has a transparent 'dolphin nose' window at distal end. The obturator housing contains a scope retention mechanism. The cannula assembly is composed of a seal system, trocar housing, transparent cannula sleeve, thermoplastic elastomer (not made with natural rubber latex) balloon, anti-migration disc and a stopcock. The seal system prevents the loss of pneumoperitoneum and can accommodate instruments 5mm in diameter. The cannula sleeve is beveled and a thermoplastic elastomer (not made with natural rubber latex) balloon is attached at the distal end. The stopcock valve is for insufflation and desufflation of the abdominal cavity. The thermoplastic elastomer (not made with natural rubber latex) balloon provides fixation (defined as force that resists the cannula from being inadvertently removed out of the patient). The anti-migration disc is on the proximal end of the cannula body and provides anchoring (defined as the force that resist the cannula from being inadvertently pushed into the patient). The devices are supplied sterile f o r single use. VersaOne™ optical trocar with fixation balloon cannula is packaged with a 5 mL syringe for inflation/deflation of the thermoplastic elastomer (not made with natural rubber latex) balloon. The thermoplastic elastomer (not made with natural rubber latex) balloon is packaged with a protective cap which is removed and discarded before device use.

INTENDED USE/INDICATIONS FOR USE:

The VersaOne™ optical trocar with fixation balloon cannula is indicated for use in general, gynecologic, thoracic and urologic minimally invasive surgical procedures.

The intended purpose of the device is to create and maintain a port of entry. The trocar may be used with or without visualization for primary and secondary insertions.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Devices	**K213818 (Subject)**	**K112349 (Predicate)**	**K924011 (Reference)**
Product Code	GCJ	GCJ	GCJ
Class	II	II	II
Components/Features	Cannula	Cannula	Cannula
	Optical Obturator	Optical Obturator	Blunt Obturator
	Stopcock	Stopcock	NA
	Fixation: Balloon	Fixation: Ribbed cannula	Fixation: Balloon
	Anchoring mechanism: anti-	NA	Anchoring mechanism: anti-

Devices	K213818 (Subject)	K112349 (Predicate)	K924011 (Reference)
	migration disc		migration disc
Dimensions	Diameter: 5 mm Lengths: 70/100/150 mm	Diameter: 5 mm Lengths: 70/100/150 mm	Diameter: 10 mm Lengths: 70/100 mm
Compatibility with surgical instruments	Usable with manual instrumentation 5 mm diameter due to self-adjusting seal system	Usable with manual instrumentation 5 mm diameter due to self-adjusting seal system	Usable with endoscopes and instruments 10 mm in diameter.
Sterilization method	Ethylene oxide	Ethylene oxide	Ethylene oxide

VersaOne™ optical trocar with fixation balloon cannula is similar to the legally marketed predicate device because the addition of balloon fixation and disc anchoring to the VersaOne™ trocar platform does not alter the intended use, indications, or user environments of the device. Applicable design control activities to ensure VersaOne™ optical trocar with fixation balloon cannula functions as intended have been completed without raising different types of questions in terms of safety and effectiveness when compared to the predicate and reference devices.

PERFORMANCE DATA:

Non-clinical performance data, verification & validation and performance testing have been conducted, including

BIOCOMPATIBILITY

Testing of the subject device performed to the following endpoints:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

BENCH TESTING

Bench testing of the subject device performed:

- Visual Inspection
- Anchor Mechanism Force
- Instrument Insertion/Removal Force
- Cannula Leak Rate
- Cannula Seal Anchoring
- Fixation Mechanism Burst Force
- Fixation Mechanism Inflation/Deflation Force
- Anchor Mechanism Activation/Deactivation Force

ANIMAL TESTING

Animal testing of the subject device performed:

- Fixation Force

- Removal Force

Side-by-side (subject, predicate, reference and informational devices) animal testing of the subject device performed:

- Cavity Access
- Tissue Visualization
- Establish/Maintain Pneumoperitoneum
- Instrument Manipulation

Clinical performance data– No clinical study has been performed.

CONCLUSION:

Based upon the supporting data contained in this submission, we concluded that VersaOne™ optical trocar with fixation balloon cannula is as safe and effective as the legally marketed predicate cleared in K112349 (S.E. September 1, 2011) and does not raise different questions of safety and effectiveness than the predicate device.