



Food and Drug Administration
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January 22, 2016

Covidien
Trang Huynh
Senior Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K152149
Trade/Device Name: VersaOne™ V2 Bladed Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 15, 2016
Received: January 20, 2016

Dear Trang Huynh:

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" (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 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 yours,

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

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

Indications for Use

510(k) Number (if known)

K152149

Device Name

VersaOne™ Bladed Trocar

Indications for Use (Describe)

indicated for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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510(k) Summary

This 510(k) summary information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

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DATE PREPARED: July 30, 2015

TRADE/PROPRIETARY NAME: VersaOne™ Bladed Trocar

COMMON/USUAL NAME: Surgical Trocar

CLASSIFICATION NAME: Endoscope and Accessories

PRODUCT CODE: GCJ

FDA PANEL NUMBER: 78

CLASS CODE: Pursuant to 21 CFR 876.1500, Class II device

PREDICATE DEVICES: Autosuture™ Modified Versaport™ Trocar with Fixation Sleeve (K062326)
Versaport™ V2 Bladeless Optical (K112349)

PURPOSE OF SUBMISSION: Obtain market clearance for VersaOne™ Bladed Trocar 5mm

INTENDED USE: Indicated for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry

DEVICE DESCRIPTION: VersaOne™ Bladed Trocar is available in diameter 5mm, cannula fixation and smooth, and length standard and short. VersaOne™ Bladed Trocar consists of an obturator component with a bladed tip and a cannula assembly. The devices are supplied sterile single-use.



TECHNOLOGICAL / DESIGN CHARACTERISTICS: VersaOne™ 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, transparent cannula sleeve, and a stopcock. The seal system prevents loss of Pneumoperitoneum when instruments are inserted or withdrawn. The cannula sleeve has a bevel shaped at the distal end to reduce penetration forces during insertion and transparent for better visualization. The stopcock valve is for insufflation and desufflation.

MATERIALS: The biocompatibility evaluation was conducted in accordance with ISO 10993-1. Acceptable results demonstrated VersaOne™ Bladed Trocar complies with ISO 10993-1 standard.

PERFORMANCE DATA: Results from performance testing demonstrated the proposed VersaOne™ Bladed Trocar perform to specifications and comparable to predicate devices K062326 and K112349.

CONCLUSION: VersaOne™ Bladed Trocar is substantially equivalent to predicates devices in terms of indications for use, contraindications, technological characteristics, labeling, sterilization, shelf life, biocompatibility, and performance.
