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 1, 2016

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

Re: K160230
Trade/Device Name: VersaOne ™ Optical Trocar 15mm
VersaOne ™ Bladeless Trocar 15mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 29, 2016
Received: February 1, 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" (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 yours,

Jennifer R. Stevenson -A

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)*
K160230

Device Name
VersaOne™ Optical Trocar and VersaOne™ Bladeless Trocar

Indications for Use *(Describe)*
The VersaOne™ 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.

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)*

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.

SUBMITTER:	Medtronic Covidien 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Ms. Trang Huynh, MS. Senior Specialist, Regulatory Affairs Phone: (203) 492-7473 Fax: (203) 492-5029 Email: trang.huynh27@medtronic.com
DATE PREPARED:	January 29, 2016
PRODUCT CODE:	GCJ
REGULATION NUMBER:	78
CLASS CODE:	Class II, Pursuant to 21 CFR 876.1500
CLASSIFICATION NAME:	Endoscope and Accessories
TRADE/PROPRIETARY NAME:	VersaOne™ Optical Trocar 15mm VersaOne™ Bladeless Trocar 15mm
COMMON/USUAL NAME:	Surgical Trocar
PREDICATE DEVICES:	Versaport™ V2 Bladeless Optical (K130435) VersaOne™ Bladeless Trocar (K151548) Autosuture™ Versaport™ Plus Bladeless Trocar (K081169)

INTENDED USE:	The **VersaOne™ 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.
DEVICE DESCRIPTION:	**VersaOne™ Optical Trocar 15mm** is available in 15mm diameter with a transparent fixation cannula and standard (100mm) length. The VersaOne™ Optical Trocar 15mm consists of an obturator component with a bladeless tip and a cannula assembly. The obturator has a dolphin nose (conical) shaped bladeless tip with transparent window at distal end. The transparent window at distal end of the obturator allows optical entry 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 seal system prevents loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system accommodates instruments ranging from 5mm to 15mm in diameter. The 15mm trocar housing is removable for specimen retrieval. The cannula sleeve has a bevel shape at the distal end to reduce penetration forces during insertion and transparent for better visualization. The stopcock valve is for insufflation and desufflation. The devices are supplied sterile single-use. The VersaOne™ Optical Trocar 15mm is sterilized via Ethylene Oxide (EtO) sterilization method. The packaging configuration is one device packed in a sealed Nylon / Tyvek breather pouch, six pouches per display box, and both pouch and display box have appropriate labeling. **VersaOne™ Bladeless Trocar 15mm** is available in two lengths (long (150mm) and standard (100mm)); both are 15mm in diameter and contain transparent fixation cannulas. VersaOne™ Bladeless Trocar consists of an obturator component with a bladeless tip and a cannula assembly. The obturator has a dolphin nose (conical) shaped bladeless tip. The cannula assembly is composed of a seal system, trocar housing, transparent cannula sleeve, and a stopcock. The seal system prevents loss of pneumoperitoneum when instruments are inserted or withdrawn. The seal system accommodates instruments ranging from 5mm to 15mm in diameter. The 15mm trocar housing is removable for specimen retrieval. The cannula sleeve has a bevel shape at the distal end to reduce penetration forces during insertion and transparent for better visualization. The stopcock valve is for insufflation and desufflation. The devices are supplied sterile single-use. The VersaOne™ Bladeless Trocar 15mm is sterilized via Ethylene Oxide (EtO) sterilization method. The packaging configuration is one device packed in a sealed Nylon / Tyvek breather pouch, six pouches per display box, and both pouch and display box have appropriate labeling.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES:	Modifications to the design and materials of the current Versaport™ V2 Bladeless Optical (K130435) and VersaOne™ Bladeless Trocar (K151548) have created new product codes (catalog numbers) to be launched as the VersaOne™ Optical Trocar 15mm and VersaOne™ Bladeless Trocar 15mm respectively. The modifications include: o Larger diameter of the cannula and obturator to accommodate a 15mm instrument o New seal system and material to accommodate instruments sizes ranging from 5mm to 15mm Sterilization assessment/evaluation was performed to confirm EtO sterilization equivalency to the predicate devices with respect to sterilization processes per ISO 11135 requirements and EtO residuals per ISO 10993-7 requirements. Shelf life assessment/evaluation was performed per Covidien standard operating procedures to confirm product performance overtime. Biocompatibility testing was performed to confirm that all components are comprised of materials that are in accordance with ISO 10993-1 for their intended patient contact profile. Performance testing including ex vivo (bench) and in vivo (animal) was performed to compare the functional performance of the proposed devices and the predicate devices. o Ex vivo testing that supports the intended use of this device includes: ▪ Leak rate ▪ Insertion force ▪ Removal force ▪ Penetration force ▪ Fixation force o In vivo testing that supports the intended use of the device includes: ▪ Penetration force ▪ Fixation force
CONCLUSION:	The results of testing demonstrate the modified VersaOne™ Optical Trocar 15mm and VersaOne™ Bladeless Trocar 15mm are substantially equivalent to the legally marketed