



Food and Drug Administration
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April 5, 2016

Surgical Instrument Service and Savings
Ms. Brandi Panteleon
Director, Quality Assurance and Regulatory Affairs
2747 SW 6th St.
Redmond, Oregon 97756

Re: K153258

Trade/Device Name: Medline Renewal Reprocessed Versaport V2 Bladeless Optical
Trocars

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: NLM

Dated: March 7, 2016

Received: March 8, 2016

Dear Ms. Panteleon:

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

Reprocessed Single-Use Device Models Included in Clearance:

Manufacturer Model No.	Description	Diameter x Length
ONB5STF	Optical bladeless Standard Trocar with Fixation Cannula	5- x 100-mm
ONB5SHF	Optical bladeless Short Trocar with Fixation Cannula	5- x 70-mm
ONB5LGF	Optical bladeless Standard Trocar with Fixation Cannula	5- x 150-mm
ONBFCA5LG	Long Fixation Cannula	5- x 150-mm
ONBFCA5SH	Short Fixation Cannula	5- x 70-mm
ONBFCA5ST	Standard Fixation Cannula	5- x 100-mm
ONB11STF	Optical bladeless Standard Trocar with Fixation Cannula	11- x 100-mm
ONB11LGF	Optical bladeless Long Trocar with Fixation Cannula	11- x 150-mm
ONBFCA11ST	Standard Fixation Cannula	11- x 100-mm
ONB12STF	Optical bladeless Standard Trocar with Fixation Cannula	12- x 100-mm
ONB12LGF	Optical bladeless Long Trocar with Fixation Cannula	12- x 150-mm
ONB12SHF	Optical bladeless Short Trocar with Fixation Cannula	12- x 70-mm
ONB12STS	Optical bladeless Standard Trocar with Smooth Cannula	12- x 100-mm
ONBFCA12ST	Standard Fixation Cannula	12- x 100- mm
ONBFCA12LG	Long Fixation Cannula	12- x 150- mm

Indications for Use

510(k) Number (if known)
K153258

Device Name
Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar

Indications for Use (Describe)

The Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar is 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.

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.

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510(k) Summary K153258

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Director, QA/RA P: 541-516-4180 F: 541-923-3375 E: bpanteleon@medline.com
Prepared by	Stephanie Mays Technical Writer P: 541-516-4205 F: 541-923-3375 E: smays@medline.com
Date Prepared	November 9, 2015
Device Names	Proprietary Name: Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar Common Name: Surgical Trocar
Classification	Laparoscope, General & Plastic Surgery, Reprocessed Product code: NLM Class: Class II, non-exempt Classification Number: 21 CFR § 876.1500
Predicate Device	K112349 Covidien Versaport V2 Bladeless Optical Trocar (11-mm and 12-mm trocars)
Reference Device	K130435 Covidien Versaport V2 Bladeless Optical Trocar (5-mm trocars)
Device Description	The Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar 5-mm, 11-mm and 12-mm, with transparent cannula and obturator, allows optical entry for visualization of tissue layers during insertion. It is available in standard (100 mm), short (70 mm) and long (150 mm) cannula lengths. The obturator housing contains a scope retention mechanism and 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 5-mm, 11-mm and 12-mm Versaport seal system accommodate instruments indicated as 5-mm up to 11-mm and 12-mm respectively.
Intended Use	The Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar is 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.
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject device are identical to the predicate device. The proposed device is a reprocessed version of the predicate device.

Performance Testing

The functional characteristics of the proposed device have been evaluated and were found to be substantially equivalent to the predicate device based on the following tests:

- Simulated use and artificial soiling;
- Functional performance studies:
 - Seal leakage;
 - Seal drag;
 - Surface roughness;
 - Visualization.
- Cleaning:
 - Protein and carbohydrates;
 - Visual inspection;
 - Cleaning performance qualification.
- Biocompatibility:
 - Cytotoxicity (direct and in-direct patient contacting);
 - Irritation (direct and in-direct patient contacting);
 - Sensitization (direct and in-direct patient contacting);
 - Material-mediated pyrogenicity (direct and in-direct patient contacting); and
 - Acute systemic toxicity (direct and in-direct patient contacting).
- Sterilization and packaging validations:
 - Bioburden enumeration testing;
 - Ethylene oxide and ethylene chlorohydrin residuals testing
- Product stability.

	Manufacturer Model No.	Description	Diameter x Length
Device models	ONB5STF	Optical bladeless Standard Trocar with Fixation Cannula	5- x 100-mm
	ONB5SHF	Optical bladeless Short Trocar with Fixation Cannula	5- x 70-mm
	ONB5LGF	Optical bladeless Standard Trocar with Fixation Cannula	5- x 150-mm
	ONBFCA5LG	Long Fixation Cannula	5- x 150-mm
	ONBFCA5SH	Short Fixation Cannula	5- x 70-mm
	ONBFCA5ST	Standard Fixation Cannula	5- x 100-mm
	ONB11STF	Optical bladeless Standard Trocar with Fixation Cannula	11- x 100-mm
	ONB11LGF	Optical bladeless Long Trocar with Fixation Cannula	11- x 150-mm
	ONBFCA11ST	Standard Fixation Cannula	11- x 100-mm
	ONB12STF	Optical bladeless Standard Trocar with Fixation Cannula	12- x 100-mm
	ONB12LGF	Optical bladeless Long Trocar with Fixation Cannula	12- x 150-mm
	ONB12SHF	Optical bladeless Short Trocar with Fixation Cannula	12- x 70-mm
	ONB12STS	Optical bladeless Standard Trocar with Smooth Cannula	12- x 100-mm
	ONBFCA12ST	Standard Fixation Cannula	12- x 100- mm
	ONBFCA12LG	Long Fixation Cannula	12- x 150- mm



K153258

Conclusion

In accordance with 21 CFR Part 807, and based on a comparison of 'Indications for Use,' technological characteristics and performance data, Medline ReNewal concludes that the proposed Medline ReNewal Reprocessed Versaport V2 Bladeless Optical Trocar is substantially equivalent to the predicate device.



K153258

Predicate, Reference, and Medline ReNewal Reprocessed Covidien Versaport V2 Bladeless Optical Trocar device comparison chart.

Device Characteristic	Predicate Device	Reference Device	Proposed Device	Comparison Analysis
	Covidien Versaport Bladeless Optical Trocar	Covidien Versaport V2 Bladeless Optical Trocar	Medline ReNewal Versaport Bladeless Optical Trocar	
510(k) Number	K112349	K130435	K153258	NA
Intended Use/Indications for Use	The Versaport Bladeless Optical Trocar is 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 Versaport V2 Bladeless Optical Trocar is 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 Medline ReNewal Reprocessed Versaport Bladeless Optical Trocar is 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.	Same
Design Configuration and Model	5-mm diameter in models: ONB5STF (100 mm) ONB5SHF (70 mm) ONB5LGF (150 mm) ONBFCA5LG (150 mm) ONBFCA5SH (70 mm) ONBFCA5ST (100 mm)	NA	5-mm diameter in models: ONB5STF (100 mm) ONB5SHF (70 mm) ONB5LGF (150 mm) ONBFCA5LG (150 mm) ONBFCA5SH (70 mm) ONBFCA5ST (100 mm)	same
	NA	11-mm diameter in models: ONB11STF (100 mm) ONB11LGF (150 mm) ONBFCA11ST (100 mm)	11-mm diameter in models: ONB11STF (100 mm) ONB11LGF (150 mm) ONBFCA11ST (100 mm)	Same

Continued

Predicate, Reference, and Medline ReNewal Reprocessed Covidien Versaport Bladeless Optical Trocar device comparison chart (concluded).

Device Characteristic	Predicate Device	Reference Device	Proposed Device	Comparison Analysis
	Covidien Versaport V2 Bladeless Optical Trocar	Covidien Versaport V2 Bladeless Optical Trocar	Medline ReNewal Versaport Bladeless Optical Trocar	
Design Configuration and Model (concluded)	NA	12-mm diameter in models: ONB12STF (100 mm) ONB12LGF (150 mm) ONB12SHF (70 mm) ONB12STS (100 mm) ONBFCA12ST (100 mm) ONBFCA12LG (150 mm)	12-mm diameter in models: ONB12STF (100 mm) ONB12LGF (150 mm) ONB12SHF (70 mm) ONB12STS (100 mm) ONBFCA12ST (100 mm) ONBFCA12LG (150 mm)	Same
Technological Characteristics	Transparent cannula, bladeless obturator with transparent optical window at distal end, obturator housing scope retention mechanism and external interlocking snaps. Scope retention mechanism is within the obturator housing for secured insertion and retention of appropriately sized 0° laparoscope for visualization of tissue layers during insertion into body cavity. Three-way stopcock for insufflation and rapid desufflation. External interlocking snaps secure obturator to the cannula.	Transparent cannula, bladeless obturator with transparent optical window at distal end, obturator housing scope retention mechanism and external interlocking snaps. Scope retention mechanism is within the obturator housing for secured insertion and retention of appropriately sized 0° laparoscope for visualization of tissue layers during insertion into body cavity. Three-way stopcock for insufflation and rapid desufflation. External interlocking snaps secure obturator to the cannula.	Transparent cannula, bladeless obturator with transparent optical window at distal end, obturator housing scope retention mechanism and external interlocking snaps. Scope retention mechanism is within the obturator housing for secured insertion and retention of appropriately sized 0° laparoscope for visualization of tissue layers during insertion into body cavity. Three-way stopcock for insufflation and rapid desufflation. External interlocking snaps secure obturator to the cannula.	Same