DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 6, 2016

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

Re: K160740
Trade/Device Name: Medline Renewal Reprocessed Endopath Xcel Trocar with Optiview Technology
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NLM
Dated: March 14, 2016
Received: March 17, 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:

Device Model	Device Name	Original Manufacturer
2B5ST	ENDOPATH XCEL® Bladeless Trocar with OPTIVIEW Technology	Ethicon
2B5LT	ENDOPATH XCEL® Bladeless Trocar with OPTIVIEW Technology	Ethicon
2B5XT	ENDOPATH XCEL® Bladeless Trocar with OPTIVIEW Technology	Ethicon
2CB5ST	ENDOPATH XCEL® Universal Sleeve with OPTIVIEW Technology	Ethicon
2CB5LT	ENDOPATH XCEL® Universal Sleeve with OPTIVIEW Technology	Ethicon

4.0 Indications for Use

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)*
TBD K160740

Device Name
Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.
The Medline ReNewal Reprocessed ENDOPATH XCEL Universal Trocar Stability Sleeve with OPTIVIEW Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

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.

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5.0 510(k) Summary

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Director, Quality Assurance and Regulatory Affairs P: 541-516-4180 F: 541-923-3375 E: bpanteleon@medline.com
Prepared by	Stephanie Boyle Mays Technical Writer P: 541-516-4205 F: 541-923-3375 E: smays@medline.com
Date Prepared	March 11, 2016
Device Names	Proprietary Name: Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology Common Name: Surgical Trocar Model No.: 2B5ST, 2B5LT and 2B5XT ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology and 2CB5ST and 2CB5LT ENDOPATH XCEL Universal Sleeve with OPTIVIEW Technology
Classification	Laparoscope, General & Plastic Surgery, Reprocessed Product code: NLM Class: Class II, non-exempt Regulation: Part 876.1500 of Title 21 of the Code of Federal Regulations
Predicate Device	K122511 ENDOPATH XCEL Trocar with OPTIVIEW Technology
Device Description	The Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology devices are sterile, single-patient use endoscopic devices used to create an access port to the inside of the body cavity to perform endoscopic surgery. The trocars accommodate instruments that are 5-mm in diameter. The trocars contain two seals, an outer integrated removable self-adjusting seal and an integrated seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation. The trocars contain OPTIVIEW Technology that reduces the incidence of trocar-induced endoscope lens smudging during endoscope insertion. Endoscope smudging occurs when bodily fluids and debris smear across the endoscope lens during a laparoscopic procedure. Trocar-induced smudging occurs when these bodily fluids and debris are deposited within the trocar's seal system when an endoscope or instrument has been exchanged through the trocar.

Indication for Use	The Medline ReNewal Reprocessed ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions. The Medline ReNewal Reprocessed ENDOPATH XCEL Universal Trocar Stability Sleeve with OPTIVIEW Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.
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; ○ endoscope smudge; and ○ Visualization. • Cleaning: ○ protein and carbohydrates; ○ visual inspection; and ○ cleaning performance qualification. • Biocompatibility: ○ cytotoxicity (direct and indirect); ○ irritation (whole device); ○ sensitization (whole device) ○ pyrogenicity (direct and indirect); and ○ acute systemic toxicity (direct and indirect). • Sterilization and packaging validations: ○ bioburden enumeration testing; and ○ ethylene oxide and ethylene chlorohydrin residuals testing. • Product stability.
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 ENDOPATH XCEL Trocar with OPTIVIEW Technology is substantially equivalent to the predicate device.

Table 1: Predicate and Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology comparison chart.

Device Characteristic	Predicate Device	Proposed Device	Comparison Analysis
	Ethicon ENDOPATH XCEL Trocar with OPTIVIEW Technology	**Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology**	
510(k) Number	K122511	~~TBD~~ K160740	NA[a]
Indications for Use	The ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions. The ENDOPATH XCEL Universal Trocar Stability Sleeve with OPTIVIEW Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.	The Medline ReNewal Reprocessed ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions. The Medline ReNewal Reprocessed ENDOPATH XCEL Universal Trocar Stability Sleeve with OPTIVIEW Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.	Same
Design Configuration and Models	ENDOPATH XCEL with OPTIVIEW Technology **Bladeless Trocar models:** • 2B5ST Trocar, 5- x 75-mm stability sleeve; • 2B5LT Trocar, 5- x 100-mm, stability sleeve; • 2B5XT Trocar, 5- x 150-mm, stability sleeve.	Medline ReNewal Reprocessed ENDOPATH XCEL with OPTIVIEW Technology **Bladeless Trocar models:** • 2B5ST Trocar, 5- x 75-mm stability sleeve; • 2B5LT Trocar, 5- x 100-mm, stability sleeve; • 2B5XT Trocar, 5- x 150-mm, stability sleeve.	

continued

Table 1: Predicate and Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology comparison chart (continued).

Device Characteristic	Predicate Device	Proposed Device	Comparison Analysis
	Ethicon ENDOPATH XCEL Trocar with OPTIVIEW Technology	**Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology**	
Design Configuration and Model (concluded)	**Universal Trocar Stability Sleeve models**: • 2CB5ST 5- x 75-mm Sleeve (cannula); • 2CB5LT 5- x 100-mm Sleeve (cannula)	**Universal Trocar Stability Sleeve models**: • 2CB5ST 5- x 75-mm Sleeve (cannula); • 2CB5LT 5- x 100-mm Sleeve (cannula)	Same
Technological Attributes	ENDOPATH XCEL Trocars with OPTIVIEW Technology consist of two components: a sleeve and an obturator. The sleeve and obturator are used to create the access port. The obturator is a subsystem used to assist in the process of installing the sleeve port through the body tissue. After installation, the obturator is not required for trocar performance. The bladeless trocar obturators accommodate an appropriately sized 0° endoscope and provide visibility of individual tissue layers during insertion. The sleeve has an integrated two-seal system for maintaining pneumoperitoneum. The trocar sleeves contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments 5-mm in diameter and an internal seal. Together these two	The Medline ReNewal Reprocessed ENDOPATH XCEL Trocars with OPTIVIEW Technology consist of two components: a sleeve and an obturator. The sleeve and obturator are used to create the access port. The obturator is a subsystem used to assist in the process of installing the sleeve port through the body tissue. After installation, the obturator is not required for trocar performance. The bladeless trocar obturators accommodate an appropriately sized 0° endoscope and provide visibility of individual tissue layers during insertion. The sleeve has an integrated two-seal system for maintaining pneumoperitoneum. The trocar sleeves contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments 5-mm in diameter and an internal seal. Together these two	Same

(*continued*)

Table 1: Predicate and Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology comparison chart (concluded).

Device Characteristic	Predicate Device	Proposed Device	Comparison Analysis
	Ethicon ENDOPATH XCEL Trocar with OPTIVIEW Technology	**Medline ReNewal Reprocessed ENDOPATH XCEL Trocar with OPTIVIEW Technology**	
Technological Characteristics (concluded)	seals minimize gas leakage 5-mm in when instruments are inserted through or completely withdrawn from the trocar. The sleeve has a welded stopcock assembly, which is compatible with standard Luer lock fittings, and provides attachment for gas insufflation and desufflation of the pneumoperitoneum. The sleeve cannula contains integrated stability threads for abdominal wall retention.	seals minimize gas leakage 5-mm in when instruments are inserted through or completely withdrawn from the trocar. The sleeve has a welded stopcock assembly, which is compatible with standard Luer lock fittings, and provides attachment for gas insufflation and desufflation of the pneumoperitoneum. The sleeve cannula contains integrated stability threads for abdominal wall retention.	