DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 3, 2017

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

Re: K161358
Trade/Device Name: Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: July 27, 2017
Received: July 28, 2017

Dear Brandi 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,

Michael J. Ryan -S

for Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K161358

Device Name
Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are accessories for use with the Stryker Neptune 2 Waste Management System, specifically the rover.
The Neptune 2 Waste Management system is intended to be used in the operating room, pathology laboratories, surgical centers and doctor's offices to collect and dispose of surgical fluid waste and to collect smoke generated by electrocautery or laser devices.

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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K161358 Summary

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave 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
Date Prepared	Aug 2, 2017
Device Names	Proprietary Name: Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds Common Name: Portable suction and smoke evacuation device (component)
Classification	Classification: Class II Regulation Number: 878.4780 Product Code: JCX
Device Models	• 0702-025-000 Neptune 2 Single-Port Manifold; • 0702-020-000 Neptune 2 4-Port Manifold; and • 0702-020-001 Neptune 2 Specimen Collection 4-Port Manifold.
Predicate Device	K132671 – Stryker Neptune 2 Waste Management System Manifolds
Device Description	The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are non-patient contacting, non-sterile, disposable devices that provide a fluid path from the suction tubing lines of a Stryker Neptune 2 Waste Management System to the receiving collection canisters of this system.
Statement of Intended Use	The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are accessories for use with the Stryker Neptune 2 Waste Management System, specifically the rover. The Neptune 2 Waste Management system is intended to be used in the operating room, pathology laboratories, surgical centers and doctor's offices to collect and dispose of surgical fluid waste and to collect smoke generated by electrocautery or laser devices.

Technological Characteristics	The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are available in the following configurations: Single-Port Manifold, Four-Port Manifold and Four-Port Manifold with Specimen Collection. All three design configurations attach to the receptacle canister of a Stryker Neptune 2 Waste Management System rover. The manifolds then act as conduits between the system's suction tubing lines, which connect to the manifold port(s), and the system's 4L and 20L receiving canisters. The proposed device is a reprocessed version of the predicate device manifolds.
Performance Testing	The functional characteristics of the Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds have been evaluated based on the following tests: • Functional performance studies: o simulated use and artificial soiling; o structural integrity; o installation and removal; o vacuum/sealing; o leakage – backflow prevention valve (use); o leakage – backflow prevention valve (disposal); o leakage – drip-reduction valve; o leakage – mating components; o specimen collection; o performance studies post accelerated aging. • Cleaning: o visual inspection; o cleaning efficacy (residual protein and residual carbohydrate); o Soil characterization. • Intermediate level disinfection
Conclusion	The results of the nonclinical tests performed demonstrated that the Medline ReNewal Reprocessed Stryker Neptune 2 Manifold is as safe, as effective, and performs as well or better than the legally marketed predicate Stryker Neptune 2 Manifold. Based on these results and a comparison of the indications for use, intended use and technological characteristics, the two devices are substantially equivalent.

Continued

Table 1: Predicate and Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	Stryker Neptune 2 Waste Management System Manifolds	**Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds**	**Same device; original and reprocessed**
510(k) Number	K132671	TBD	N/A
Product Name	Stryker Neptune 2 Waste Management System Manifolds	Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds	N/A
Intended Use	The Stryker Neptune 2 Waste Management System Manifolds are accessories for use with the Stryker Neptune 2 Waste Management System, specifically the rover. The Neptune 2 Waste Management system is intended to be used in the operating room, pathology laboratories, surgical centers and doctor's offices to collect and dispose of surgical fluid waste and to collect smoke generated by electrocautery or laser devices.	The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are accessories for use with the Stryker Neptune 2 Waste Management System, specifically the rover. The Neptune 2 Waste Management system is intended to be used in the operating room, pathology laboratories, surgical centers and doctor's offices to collect and dispose of surgical fluid waste and to collect smoke generated by electrocautery or laser devices.	Same
Technological Characteristics	The Stryker Neptune 2 Waste Management System Manifolds are available in the following configurations: Single-Port Manifold, Four-Port Manifold and Four-Port Manifold with Specimen Collection. All three of these configurations are designed to attach to the receptacle canister of a Stryker Neptune 2 Waste Management System rover. The manifolds then act as conduits between the system's suction tubing lines, which connect to the manifold port(s), and the system's 4L and 20L receiving canisters.	The Medline ReNewal Reprocessed Stryker Neptune 2 Manifolds are available in the following configurations: Single-Port Manifold, Four-Port Manifold and Four-Port Manifold with Specimen Collection. All three of these configurations are designed to attach to the receptacle canister of a Stryker Neptune 2 Waste Management System rover. The manifolds then act as conduits between the system's suction tubing lines, which connect to the manifold port(s), and the system's 4L and 20L receiving canisters.	Same