October 18, 2017

Surgical Instrument Service and Savings (dba Medline ReNewal)
Ms. Stephanie Boyle Mays
Regulatory Specialist, Quality Assurance and Regulatory Affairs
1500 NE Hemlock Ave.
Redmond, Oregon 97756

Re: K172608
Trade/Device Name: Medline ReNewal Reprocessed Stryker SERF AS Energy Probes (Models:279-351-100, 279-351-230, 279-351-250, 279-351-300,279-351-400, and 279-401-100)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: August 30, 2017
Received: August 31, 2017

Dear Ms. Mays:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172608

Device Name
Medline ReNewal Reprocessed Stryker SERFAS Energy Probes (models: 279-351-100, 279-351-230, 279-351-250, 279-351-300, 279-351-400, and 279-401-100)

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Stryker SERFAS Energy Probe is a disposable, radio frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery of the knee, shoulder, ankle, hip, elbow, and wrist.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Reprocessed Single-Use Device Models Included in Clearance:

Device Model	Device Name	Original Manufacturer
279-351-100	90-S SERFAS Energy Suction Probe 3.5 mm	Stryker
279-351-230	30-S SERFAS Energy Suction Probe 3.5 mm	Stryker
279-351-250	50-S SERFAS Energy Suction Probe 3.5 mm	Stryker
279-351-300	Super 90-S SERFAS Energy Suction Probe 3.5 mm	Stryker
279-351-400	90-S Accelerator SERFAS Energy Suction Probe 3.5 mm	Stryker
279-401-100	90-S MAX SERFAS Energy Suction Probe 4.0 mm	Stryker

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave. Redmond, OR 97756	
Date Prepared	August 30, 2017	
Contact Name/Prepared by	Stephanie Boyle Mays Regulatory Affairs Specialist, Regulatory Affairs P: 541-516-4205/F: 541-923-3375 E: smays@medline.com	
Device Name and Classification	Propriety/Trade Name:	Medline ReNewal Reprocessed Stryker SERFAS Energy Probes, models: 279-351-100, 279-351-230, 279-351-250, 279-351-300, 279-351-400, and 279-401-100
	Common Name:	Electrosurgical cutting and coagulation device and accessories
	Classification:	Class II
	Regulation Number:	21 CFR § 878.4400
	Product Code:	NUJ
	Panel:	General & Plastic Surgery
Predicate Device and Classification	510(k) Number	K041810
	Propriety/Trade Name:	Stryker SERFAS Energy Probes, models: 279-351-100, 279-351-230, 279-351-250, 279-351-300, 279-351-400, and 279-401-100
	Common Name:	Electrosurgical cutting and coagulation device and accessories
	Classification:	Class II
	Regulation Number:	21 CFR § 878.4400
	Product Code:	GEI
	Panel:	General & Plastic Surgery
	Manufacturer:	Stryker Endoscopy, 5900 Optical Ct., San Jose, CA 95138
Intended Use	The Medline ReNewal Reprocessed Stryker SERFAS Energy Probe is a disposable, radio frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery of the knee, shoulder, ankle, hip, elbow, and wrist.	
Product Description	The Medline ReNewal Reprocessed Stryker SERFAS Energy Probes are single-use devices that have been cleaned, disinfected, inspected, refurbished, tested, packaged, labeled, and sterilized. All models can be operated with integrated finger switches on the device handle to control ablation, coagulation and power level. Each model also has a suction line that removes tissue and fluids from the surgical site. In addition, the models can be operated with foot switches, which offer another mode with which to	

	control ablation, coagulation, and the power setting. The devices are connected to the appropriate generator by a connector cable. The generators and the foot switches are not included in the scope of this project, and they will not be reprocessed.
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate device. The proposed devices are a reprocessed version of the predicate K041810 Stryker SERFAS Energy Probes. The predicate devices were used to support intended use, technological characteristics, and functional performance specifications.

510(k) Substantial Equivalence Chart

Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Stryker SERFAS Energy Probes	**Medline ReNewal Reprocessed Stryker SERFAS Energy Probes**	**As Stated**
510(k)	K041810	TBD	Not applicable
Model Numbers	• 279-351-100 • 279-351-230 • 279-351-250 • 279-351-300 • 279-351-400 • 279-401-100	• 279-351-100 • 279-351-230 • 279-351-250 • 279-351-300 • 279-351-400 • 279-401-100	Same
Intended Use	The SERFAS Energy Probe is a disposable, radio frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery of the knee, shoulder, ankle, hip, elbow, and wrist. The probe includes an energy-transferring cable as well as several different tip configurations and suction probes which are capable of providing simultaneous fluid aspirations.	The Medline ReNewal Reprocessed SERFAS Energy Probe is a disposable, radio frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery of the knee, shoulder, ankle, hip, elbow, and wrist. The probe includes an energy-transferring cable as well as several different tip configurations and suction probes which are capable of providing simultaneous fluid aspirations.	Same

510(k) Substantial Equivalence Chart (concluded)			
Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Stryker SERFAS Energy Probes	Medline ReNewal Reprocessed Stryker SERFAS Energy Probes	As Stated
Product Description	The Stryker SERFAS Energy Probes are single-use devices. All models can be operated with integrated finger switches on the device handle to control ablation, coagulation and power level. Each model also has a suction line that removes tissue and fluids from the surgical site. In addition, the models can be operated with foot switches, which offer another mode with which to control ablation, coagulation, and the power setting. The devices are connected to the appropriate generator by a connector cable.	The Medline ReNewal Reprocessed Stryker SERFAS Energy Probes are single-use devices that have been cleaned, disinfected, inspected, refurbished, tested, packaged, labeled, and sterilized. All models can be operated with integrated finger switches on the device handle to control ablation, coagulation and power level. Each model also has a suction line that removes tissue and fluids from the surgical site. In addition, the models can be operated with foot switches, which offer another mode with which to control ablation, coagulation, and the power setting. The devices are connected to the appropriate generator by a connector cable. The generators and the foot switches are not included in the scope of this project, and they will not be reprocessed.	As stated
Power Platform	• Stryker SERFAS Energy System • Stryker Crossfire System	• Stryker SERFAS Energy System • Stryker Crossfire System	Same
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate device. The proposed devices are a reprocessed version of the predicate K041810 Stryker SERFAS Energy Probes. The predicate devices were used to support intended use, technological characteristics, and functional performance specifications.		Same

Performance Testing	The functional characteristics of the proposed Medline ReNewal Reprocessed Stryker SERFAS Energy Probe have been evaluated and found to be equivalent to the Stryker SERFAS Energy Probe predicate devices based on the following tests:
	
	• sterilization validation;
	• biocompatibility;
	  • cytotoxicity, sensitization, irritation; pyrogenicity, and acute systemic toxicity;
	• electrical testing
	  • electromagnetic compatibility (in accordance with IEC 60601-1-2);
	  • electrical safety (in accordance with IEC 60601-1 and IEC 60601-2-2); and
	  • basic safety (in accordance with IEC 60601-1 and IEC 60601-2-2)
	• performance qualification:
	  • simulated use;
	  • critical function bending equivalence test;
	  • critical function suction equivalence test;
	  • critical function thermal tissue damage equivalence test;
	  • critical function drop equivalence test;
	  • critical function device equivalence integrity; and
	  • product stability
	• cleaning;
	  • protein, and
	  • hemoglobin.

Conclusion	Based on comparisons of the intended use, technological characteristics and attributes, power platforms, and performance testing and data to the predicate devices, the Medline ReNewal Reprocessed Stryker SERFAS Energy Probes (models: 279-351-100, 279-351-230, 279-351-250, 279-351-300, 279-351-400, and 279-401-100) are substantially equivalent to the predicate Stryker SERFAS Energy Probes (models: 279-351-100, 279-351-230, 279-351-250, 279-351-300, 279-351-400, and 279-401-100).