DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 3, 2017

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

Re: K170955
Trade/Device Name: Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector, Models SCD 391 and SCD 396
Regulatory Class: Unclassified
Product Code: NLQ
Dated: June 6, 2017
Received: June 7, 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 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

~~TBD~~ K170955

Device Name

Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Devices SCD 391 and SCD 396

Indications for Use *(Describe)*

The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Devices models SCD 391 and SCD 396 are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The devices can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. The Sonicision Cordless Ultrasonic Dissection Devices can be used to coagulate isolated vessels up to 5 mm diameter.

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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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"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
SCD391	Covidien Sonicision Cordless Ultrasonic Dissector (14.5-mm jaw and 5-mm diameter x 39-cm long shaft)	Covidien
SCD396	Covidien Sonicision Cordless Ultrasonic Dissector (14.5-mm jaw and 5-mm diameter x 39-cm long shaft)	Covidien

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	March 30, 2017	
Contact person:	Ms. Stephanie Boyle Mays, BA Regulatory Affairs Specialist, Regulatory Affairs Phone: 541-516-4205 Fax: 541-923-3375 E-mail: smays@medline.com	
Device Names and Classification:	Propriety/Trade Name:	Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Devices, models SCD391 and SCD396
	Common Name:	Scalpel, ultrasonic reprocessed
	Classification:	Unclassified
	Product Code:	NLQ
	Panel:	General & Plastic Surgery
Predicate Device:	510(k) Number:	K101797
	Propriety/Trade Name:	Sonicision Cordless Ultrasonic Dissection Device, models SCD391 and SCD396
	Common Name:	Cordless ultrasonic surgical device
	Classification:	Instrument, ultrasonic surgical
	Product Code:	LFL
	Panel:	General & Plastic Surgery
	Manufacturer:	Covidien, formerly Valleylab, a division of Tyco Healthcare: 5920 Longbow Dr., Boulder, CO 80301
Device Description:	The Sonicision Cordless Ultrasonic Dissector Device, models SCD391 and SCD396, are sterile, single-use components to which the Sonicision Reusable Generator and Reusable Battery Pack attach. (The Sonicision Reusable Generator and Reusable Battery Pack are not included in this submission and will not be reprocessed by Medline ReNewal.) This component provides control for device functions such as selecting power levels, blade placement and position, grasping, coagulating and dissecting tissue. The Cordless Ultrasonic Dissection Devices can coagulate vessels up to 5 mm in diameter. Furthermore, they are designed to be inserted and extracted through a compatible 5 mm trocar when used endoscopically.	

Intended Use/Indications for Use:	The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Devices, models SCD391 and SCD396, are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The devices can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. The Sonicision Cordless Ultrasonic Dissection Devices can be used to coagulate isolated vessels up to 5 mm diameter.
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 K101797 Sonicision Cordless Ultrasonic Dissector Devices. The predicate device was used to support intended use, technological characteristics, and functional performance specifications.

510(k) Substantial Equivalence Chart

Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Covidien Sonicision Cordless Ultrasonic Dissector	**Medline ReNewal Sonicision Cordless Ultrasonic Dissector**	**As stated**
510(k)	K101797	K170955	Not Applicable
Model Numbers	SCD391, SCD396	SCD391, SCD396	Not Applicable
Intended Use/Indications for Use	The Sonicision TM Cordless Ultrasonic Dissection Device is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. The Sonicision Cordless Ultrasonic Dissection Device can be used to coagulate isolated vessels up to 5 mm in diameter.	The Medline ReNewal Reprocessed Sonicision Cordless™ Ultrasonic Dissection Devices models SCD 391 and SCD 396 are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The devices can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. The Sonicision Cordless Ultrasonic Dissection Devices can be used to coagulate isolated vessels up to 5 mm diameter.	Same

510(k) Substantial Equivalence Chart (concluded)

Device Characteristics	Predicate	Proposed	Comparison
	Covidien Sonicision Cordless Ultrasonic Dissector	**Medline ReNewal Sonicision Cordless Ultrasonic Dissector**	**As stated**
Power Platform[a]	Sonicision Battery and Generator	Sonicision Battery and Generator	Same
Technological Characteristics	The Sonicision Cordless Ultrasonic Dissectors is used to coagulate isolated vessels up to 5 mm in diameter. Device features interface with the Sonicision battery and generator.	The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissectors SCD 391 and SCD 396 are used to coagulate isolated vessels up to 5 mm in diameter. Device features interface with the Sonicision battery and generator.	Same
[a] The Sonicision Battery and Generator are not part of this submission and will not be reprocessed by Medline ReNewal. The battery and generator were cleared in K153371 (cleared March 3, 2016) and K101797 (cleared February 24, 2011).			

Performance Testing:	The functional characteristics of the proposed devices have been evaluated and found to be equivalent to the predicate devices based on the following tests:
	• simulated use;
	• grasping/pulling force;
	• cutting effectiveness/functionality;
	• drop test;
	• device integrity;
	• cutting/coagulation evaluation for a prolonged period of time;
	• thermal analysis characterization;
	• tissue sticking;
	• cleaning;
	  • protein, carbohydrates, and endotoxins;
	• biocompatibility;
	  • cytotoxicity, sensitization, irritation; pyrogenicity, and acute systemic toxicity;
	• performance qualification;
	• sterilization validation; and
	• product stability.

Conclusion:	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Sonicision Cordless Ultrasonic Dissection Devices, models SCD391 and SCD396 are substantially equivalent to the predicate devices.