July 12, 2018

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

Re: K173627
Trade/Device Name: Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector, Model SCD 13
Regulation Name: Unclassified
Regulatory Class: Class II
Product Code: NLQ
Dated: May 10, 2018
Received: May 14, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

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)*
K173627

Device Name
Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector model SCD13

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector model SCD13 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 diameter.
The Sonicision 13-cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.

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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Reprocessed Single-Use Device Model Included in Submission:

Device Model	Device Name	Original Manufacturer
SCD13	Sonicision Cordless Ultrasonic Dissector (14.5-mm jaw and 5-mm diameter x 13-cm long shaft)	Covidien

K173627 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	
Prepared by/Contact Name	Stephanie Boyle Mays Regulatory Affairs Specialist, Quality Assurance and Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • E: smays@medline.com	
Date Prepared	May 14, 2018	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector, Model SCD13
	Regulatory Name:	Scalpel, ultrasonic reprocessed
	Regulatory Class	Unclassified
	Product Code:	NLQ
	Panel:	General & Plastic Surgery
Predicate Device	510(k) number:	K153371
	Proprietary/Trade Name:	Sonicision Cordless Ultrasonic Dissection Device, SCD13
	Regulatory Name:	Instrument, ultrasonic surgical
	Classification:	Unclassified
	Product Code:	LFL
	Panel:	General & Plastic Surgery
	Manufacturer	Covidien, 5920 Longbow Dr., Boulder, CO 80301
Reference Device	510(k) number:	K170955
	Proprietary/Trade Name:	Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector, Models SCD391 and SCD 396
	Regulatory Name:	Scalpel, ultrasonic reprocessed
	Classification:	Unclassified
	Product Code:	NLQ
	Panel:	General & Plastic Surgery
	Manufacturer	Surgical Instrument Service and Savings (dba Medline ReNewal), 1500 NE Hemlock Ave., Redmond, OR 97756
Device Description	The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector model SCD13, is a sterile, single-use component 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 Device can coagulate vessels up to 5 mm in diameter. Furthermore, it is designed to be inserted and extracted through a compatible 5 mm trocar, when used endoscopically.	

Indications for Use:	The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Device model SCD13 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 diameter. The Sonicision 13-cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate and reference devices. The proposed device is a reprocessed version of the predicate K153371 Sonicision Cordless Ultrasonic Dissector SCD13 device. The predicate and reference devices were used to support intended use, technological characteristics, and functional performance specifications.

Device Characteristics	**Predicate**	**Reference**	**Proposed**	**Comparison**
	Covidien Sonicision Cordless Ultrasonic Dissector	**Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector**	**Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissector**	As Stated
510(k)	K153371	K170955	K173627	Not applicable
Model Number(s)	SCD13	SCD391, SCD396	SCD13	As stated
Indications for Use	The Sonicision 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	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	The Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Device model SCD13 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,	Proposed device same as predicate; proposed device same as reference except for additional ENT indications on proposed device

Device Characteristics	Predicate	Reference	Proposed	Comparison
Indications for Use concluded	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 Sonicision 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.	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.	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 Sonicision 13-cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.	
Power Platform[a]	Sonicision Battery and Generator	Sonicision Battery and Generator	Sonicision Battery and Generator	Same
Technological Characteristics	The Sonicision Cordless Ultrasonic Dissector is a sterile single-use device that includes the following features: •Active blade that vibrates at ultrasonic frequency and delivers the energy that provides the tissue effect. •Clamping jaw that the surgeon uses to provide pressure to vessels, tissues, or	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.	The Medline ReNewal Reprocessed Cordless Ultrasonic Dissector model SCD13 is a sterile single-use device that includes the following features: •Active blade that vibrates at ultrasonic frequency and delivers the energy that provides the tissue effect. •Clamping jaw that the surgeon uses to provide pressure to vessels, tissues, or	Same as predicate

Device Characteristics	Predicate	Reference	Proposed	Comparison
	vascular bundles as needed to deliver the desired tissue effect. •Controls for activating the delivery of ultrasonic energy and for opening and closing the clamping jaw; •Features that interface with the Sonicision generator and the Sonicision battery.		vascular bundles as needed to deliver the desired tissue effect. •Controls for activating the delivery of ultrasonic energy and for opening and closing the clamping jaw; •Features that interface with the Sonicision generator and the Sonicision battery.	
[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 - Bench	The functional characteristics of the proposed devices were compared to the performance of the primary predicate device in several bench and animal tests (see below list). The results of this testing showed comparable performance between the proposed and predicate devices.
	• simulated use;
	• grasping/pulling force;
	• cutting effectiveness/functionality;
	• drop test;
	• device integrity;
	• cutting/coagulation evaluation for a prolonged period of time;
	• tissue sticking;
	• cleaning;
	  ○ protein, carbohydrates, and endotoxins;
	• biocompatibility;
	  ○ cytotoxicity, sensitization, irritation; pyrogenicity, and acute systemic toxicity;
	• performance qualification;
	• sterilization validation;
	• product stability;
	• acute *ex vivo*
	  ○ vessel sealing verification (initial)
	  ○ ENT morphometry evaluation for thermal spread as compared to predicate device; and
	  ○ other histopathology

Performance Testing – Chronic *in vivo*	Performance of the device was also established in a 21-day chronic *in vivo* study with a porcine model. Testing included*:* ○ vessel sealing verification (initial); ○ hypertensive challenge and ○ gross pathology on necropsy (no notable hemorrhage or injury in collateral structures)

<table>
<tr><td></td><td>Tissue types and vessles evaluated to show effective sealing in arteries and veins included:
<table>
<tr><th>Tissue/Vessel Name</th><th>Vessel Size Range (mm)</th></tr>
<tr><td colspan="2">A/V Bundle</td></tr>
<tr><td>Hypogastric</td><td>2.0 - 5.0</td></tr>
<tr><td>Short Gastric</td><td>2.0 – 5.0</td></tr>
<tr><td>Gastrosplenic</td><td>Up to 5.0</td></tr>
<tr><td>Ovarian Pedicle</td><td>3.0 – 5.0</td></tr>
<tr><td colspan="2">Isolated Arteries or Veins</td></tr>
<tr><td>Splenic</td><td>Up to 5.0</td></tr>
<tr><td>Renal</td><td>4.0 – 5.0</td></tr>
</table></td></tr>
<tr><td>Conclusion</td><td>Based on comparisons of the indications for use, intended use, technological characteristics, and performance bench and perfomance chronic data to the predicate device, Medline ReNewal Reprocessed Sonicision Cordless Ultrasonic Dissection Device, model SCD13 is substantially equivalent to the predicate devices.</td></tr>
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