DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2017

Surgical Instrument Service and Savings Inc.
Brandi Panteleon
Director, Quality Assurance and Regulatory Affairs
(dba Medline ReNewal)
1500 NE Hemlock Ave.
Redmond, Oregon 97756

Re: K171324
Trade/Device Name: Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: May 4, 2017
Received: May 5, 2017

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,

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

Reprocessed Single-Use Device Models Subject to Clearance:

Model Number	Device Name/Description	Design	Original Manufacturer
ASHA 4250-01	Ambient® Super TurboVac® 90° IFS	3.75mm Shaft, 90° Tip Angle	ArthroCare
ASH 4250-01	Super TurboVac 90° IFS	3.75mm Shaft, 90° Tip Angle	ArthroCare
ASHA 4830-01	Ambient® Super MultiVac® 50° IFS	3.75mm Shaft, 50° Tip Angle	ArthroCare
ASH 4830-01	Super MultiVac® 50° IFS	3.75mm Shaft, 50° Tip Angle	ArthroCare
ASHA 3730-01	Ambient® CoVac® 70° IFS	3.0mm Shaft, 70° Tip Angle	ArthroCare
ASHA 2530-01	Ambient® CoVac® 50° IFS	3.0mm Shaft, 50° Tip Angle	ArthroCare
72202140	Dyonics RF-S Cross 50° Suction Probe	3.0mm Shaft, 50° Tip Angle	Smith & Nephew Dyonics

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)*
K171324

Device Name
Medline ReNewal Reprocessed ArthroCare ArthroWands models ASHA 4250-01; ASH 4250-01; ASHA 2530-01; ASHA 3730-01; ASHA 4830-01; and ASH 4830-01 and Medline ReNewal Reprocessed Smith & Nephew Dyonics model 72202140 Ablation Wands

Indications for Use *(Describe)*

The Medline ReNewal Reprocessed ArthroCare ArthroWands models ASHA 4250-01; ASH 4250-01; ASHA 2530-01; ASHA 3730-01; ASHA 4830-01; and ASH 4830-01 and Medline ReNewal Reprocessed Smith & Nephew Dyonics model 72202140 ablation wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

Ablation and Debridement: ACL/PCL (knee); acromioplasty (shoulder); articular cartilage (all joints); bursectomy (all joints); chondroplasty (all joints); fascia (all joints); ligament (all joints); notchplasty (knee); scar tissue (all joints); soft tissue (all joints);subacromial decompression (shoulder); synovectomy (all joints); and tendon (all joints).

Excision and Resection: acetabular labrum (hip); articular labrum (all joints); capsule (all joints); capsular release (knee); cartilage flaps (knee); cysts (all joints); discoid meniscus (knee); frozen shoulder release (shoulder); glenoidale labrum (shoulder); lateral release (knee); ligament (all joints); loose bodies (all joints); meniscal cystectomy (knee); meniscectomy (knee); plica removal (all joints); scar tissue (all joints); soft tissue (all joints); synovial membrane (all joints); tendon (all joints); triangular fibrocartilage (TFCC), (wrist); and villusectomy (knee).
Coagulation: ACL/PCL (knee); articular cartilage (all joints); carpal ligaments (wrist); glenohumeral capsule (shoulder); ligament (all joints); medial retinaculum (knee); rotator cuff (shoulder); tendon (all joints) and wrist tendons (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)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 Subject to Clearance:

Model Number	Device Name/Description	Design	Original Manufacturer
ASHA 4250-01	Ambient® Super TurboVac® 90° IFS	3.75mm Shaft, 90° Tip Angle	ArthroCare
ASH 4250-01	Super TurboVac 90° IFS	3.75mm Shaft, 90° Tip Angle	ArthroCare
ASHA 4830-01	Ambient® Super MultiVac® 50° IFS	3.75mm Shaft, 50° Tip Angle	ArthroCare
ASH 4830-01	Super MultiVac® 50° IFS	3.75mm Shaft, 50° Tip Angle	ArthroCare
ASHA 3730-01	Ambient® CoVac® 70° IFS	3.0mm Shaft, 70° Tip Angle	ArthroCare
ASHA 2530-01	Ambient® CoVac® 50° IFS	3.0mm Shaft, 50° Tip Angle	ArthroCare
72202140	Dyonics RF-S Cross 50° Suction Probe	3.0mm Shaft, 50° Tip Angle	Smith & Nephew Dyonics

K171324 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
Prepared by	Stephanie Boyle Mays Regulatory Affairs Specialist, Regulatory Affairs P: 541-516-4205 F: 541-923-3375 E: smays@medline.com
Date Prepared	April 14, 2017
Device Names	Proprietary Name: Medline ReNewal Reprocessed ArthroCare ArthroWands models ASHA 4250-01; ASH 4250-01; ASHA 2530-01; ASHA 3730-01; ASHA 4830-01; and ASH 4830-01 and Medline ReNewal Reprocessed Smith & Nephew Dyonics model 72202140 Ablation Wands Common Name: Electrosurgical device and accessories
Classification	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400) Product code: NUJ
Predicate Device	K083306 Modification to ArthroCare ArthroWands
Reference Device	K093165 ArthroCare System 1500 Controller, ArthroWands
Device Description	Ablation wands are indicated for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic procedures, including knee, shoulder, ankle, hip, elbow, and wrist joints. The device is powered by a separate generator. The generator is not included in the scope of the study and will not be reprocessed.
Intended Use	The Medline ReNewal Reprocessed ArthroCare and Smith & Nephew Dyonics Ablation Wands with integrated cables are indicated for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures.
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 K083306 Modification to ArthroCare ArthroWands. The predicate devices were used to support intended use, technological characteristics, and functional performance specifications.

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:
	• sterilization validation;
	• biocompatibility;
	  • cytotoxicity, sensitization, irritation; pyrogenicity, and acute systemic toxicity;
	• electrical testing
	  • electromagnetic compatibility (per IEC 60601-1-2);
	  • electrical safety (per IEC 60601-1 and IEC 60601-2-2); and
	  • basic safety (per 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 indications for use, intended use, technological characteristics, and performance data to the predicate devices, the Medline ReNewal Reprocessed ArthroCare and Smith & Nephew Dyonics Ablation Wands are substantially equivalent to the predicate and reference devices.

Table 1: Predicate, Reference and Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands comparison chart.

Device	Predicate	Reference	Proposed	Comparison
	Modification to ArthroCare ArthroWands	**ArthroCare System 1500 Controller, ArthroWands[a]**	**Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands[a]**	**As stated**
510(k)	K083306	K093165	TBD	N/A
Model Numbers	• ArthroCare ArthroWands: ASHA 4250-01; ASH 4250-01; ASHA 2530-01; ASHA 3730-01; ASHA 4830-01; and ASH 4830-01	• Smith & Nephew Dyonics: 72202140	• ArthroCare ArthroWands: ASHA 4250-01; ASH 4250-01; ASHA 2530-011; ASHA 3730-01; ASHA 4830-01; and ASH 4830-01 • Smith & Nephew Dyonics: 72202140	N/A
Power Platform[b]	Quantum 2 Controller	Dyonics RF Generator	Quantum 2 Controller; Dyonics RF Generator	As stated
Technological Characteristics	The ArthroCare ArthroWands and ablation wands are used to coagulate isolated vessels up to 5 mm in diameter.	The ArthroCare System 1500 Wands (Smith & Nephew Dyonics) ablation wands are used to coagulate isolated vessels up to 5 mm in diameter.	The reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics ablation wands are used to coagulate isolated vessels up to 5 mm in diameter.	Same
Indications for Use	The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.	The ArthroCare System 1500 Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.	The reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic	

Table 1: Predicate, Reference and Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands comparison chart (continued).

Device	Predicate	Reference	Proposed	Comparison
	Modification to ArthroCare ArthroWands	**ArthroCare System 1500 Controller, ArthroWands[a]**	**Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands[a]**	**As stated**
Intended Use/Indication for Use	**Ablation and Debridement:** ACL/PCL (knee); acromioplasty (shoulder); articular cartilage (all joints); bursectomy (all joints); chondroplasty (all joints); fascia (all joints); ligament (all joints); notchplasty (knee); scar tissue (all joints); soft tissue (all joints);subacromial decompression (shoulder); synovectomy (all joints); and tendon (all joints). **Excision and Resection:** acetabular labrum (hip); articular labrum (all joints); capsule (all joints); capsular release (knee); cartilage flaps (knee); cysts (all joints); discoid meniscus (knee); frozen shoulder release (shoulder); glenoidale labrum (shoulder); lateral release (knee); ligament (all joints); loose bodies (all joints); meniscal cystectomy (knee);	**Ablation and Debridement:** ACL/PCL (knee); acromioplasty (shoulder); articular cartilage (all joints); bursectomy (all joints); chondroplasty (all joints); fascia (all joints); ligament (all joints); notchplasty (knee); scar tissue (all joints); soft tissue (all joints);subacromial decompression (shoulder); synovectomy (all joints); and tendon (all joints). **Excision and Resection:** acetabular labrum (hip); articular labrum (all joints); capsule (all joints); capsular release (knee); cartilage flaps (knee); cysts (all (all joints); discoid meniscus (knee); frozen shoulder release (shoulder); glenoidale labrum (shoulder); lateral release (knee); ligament (all joints); loose bodies (all joints); meniscal cystectomy (knee);	procedures. **Ablation and Debridement:** ACL/PCL (knee); acromioplasty (shoulder); articular cartilage (all joints); bursectomy (all joints); chondroplasty (all joints); fascia (all joints); ligament (all joints); notchplasty (knee); scar tissue (all joints); soft tissue (all joints);subacromial decompression (shoulder); synovectomy (all joints); and tendon (all joints). **Excision and Resection:** acetabular labrum (hip); articular labrum (all joints); capsule (all joints); capsular release (knee); cartilage flaps (knee); cysts (all joints); discoid meniscus (knee); frozen shoulder release (shoulder); glenoidale labrum (shoulder); lateral release (knee); ligament (all joints); loose bodies (all joints);	Same

Table 1: Predicate, Reference and Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands comparison chart (concluded).

Devices	Predicate	Reference	Proposed	Comparison
	Modification to ArthroCare ArthroWands	**ArthroCare System 1500 Controller, ArthroWands[a]**	**Medline ReNewal Reprocessed ArthroCare ArthroWands and Smith & Nephew Dyonics Ablation Wands[a]**	**As stated**
Intended Use/Indication for Use (concluded)	meniscectomy (knee); plica removal (all joints); scar tissue (all joints); soft tissue (all joints); synovial membrane (all joints); tendon (all joints); triangular fibrocartilage (TFCC), (wrist); and villusectomy (knee). **Coagulation:** ACL/PCL (knee); articular cartilage (all joints); carpal ligaments (wrist); glenohumeral capsule (shoulder); ligament (all joints); medial retinaculum (knee); rotator cuff (shoulder); tendon (all joints) and wrist tendons (wrist).	meniscectomy (knee); plica removal (all joints); scar tissue (all joints); soft tissue (all joints); synovial membrane (all joints); tendon (all joints); triangular fibrocartilage (TFCC), (wrist); and villusectomy (knee). **Coagulation:** ACL/PCL (knee); articular cartilage (all joints); carpal ligaments (wrist); glenohumeral capsule (shoulder); ligament (all joints); medial retinaculum (knee); rotator cuff (shoulder); tendon (all joints) and wrist tendons (wrist).	meniscal cystectomy (knee); meniscectomy (knee); plica removal (all joints); scar tissue (all joints); soft tissue (all joints); synovial membrane (all joints); tendon (all joints); triangular fibrocartilage (TFCC), (wrist); and villusectomy (knee). **Coagulation:** ACL/PCL (knee); articular cartilage (all joints); carpal ligaments (wrist); glenohumeral capsule (shoulder); ligament (all joints); medial retinaculum (knee); rotator cuff (shoulder); tendon (all joints) and wrist tendons (wrist).	

a. The ArthroCare 15000 wand model 72202140 is sold as the Smith & Nephew Dyonics ablation wand model 72202140.
b The ArthroCare Quantum 2 Controller and Smith & Nephew Dyonics generators are not part of this submission and will not be reprocessed by Medline ReNewal. The generators were cleared in K083306 and K093165 respectively.