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

May 1, 2017

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

Re: K162751
Trade/Device Name: Medline ReNewal Reprocessed LigaSure Curved, Small Jaw Open Sealer/Divider LF1212A
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: April 19, 2017
Received: April 21, 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 -S

FDA

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	Original Manufacturer
LF1212A	LigaSure Curved, Small Jaw, Open Sealer/Divider	Covidien

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)*
K162751

Device Name
Medline ReNewal Reprocessed LigaSure Curved, Small Jaw Open Sealer/Divider LF1212A

Indications for Use *(Describe)*

The Medline ReNewal Reprocessed LigaSure Curved Small Jaw, Open Sealer/Divide LF1212A is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.
The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2 – 3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.
The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these 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)

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."

K162751 Summary

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Director, 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	September 29, 2016
Device Names	Proprietary Name: Medline ReNewal Reprocessed LigaSure Curved, Small Jaw Open Sealer/Divider LF1212A Common Name: Bipolar electrosurgical instrument
Classification	Electrosurgical cutting and coagulation device and accessories reprocessed Product code: NUJ Class: Class II, non-exempt
Predicate Device	K152286 LigaSure Curved, Small Jaw, Open Sealer/Divider LF1212A
Device Description	The Medline ReNewal Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider LF1212A is a sterile, single-use, hand-held bipolar electrosurgical instrument designed for use with compatible Covidien generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles and lymphatics during open general surgical procedures. Covidien electrosurgical generators that include vessel sealing capabilities deliver precise energy through the device to tissue for a controlled tissue response to achieve complete and permanent tissue fusion while producing minimal sticking, charring, and thermal spread to adjacent tissue. The surgeon first grasps the vessel or tissue with the jaws of the instrument. Once the surgeon is confident that the instrument is placed correctly, he or she initiates a seal by pressing a hand switch or footswitch. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) or tissue bundles interposed between the jaws of the instrument. Once the seal cycle is complete, the surgeon actuates a blade within the instrument to divide tissue along the seal line. The 10-foot cord, cable connector, and generator are not reprocessed by Medline ReNewal.

Intended Use	The Medline ReNewal Reprocessed LigaSure Curved Small Jaw, Open Sealer/Divide LF1212A is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2 – 3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these 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 devices. K152286 LigaSure Curved, Small Jaw, Open Sealer/Divider LF1212A was used as the primary predicate 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: • electrical safety and electromagnetic compatibility in accordance with IEC 60601-2-2 and 60601-1-2; • simulated use; • device integrity; • blade trigger advance/return; • activation button • device recognition; • thermal analysis characterization; • tissue sticking; • blade sharpness; • transient cooling analysis • burst pressure; • histopathology; • seal quality; • Cleaning: o protein, o carbohydrates, and o endotoxin; • Biocompatibility: o cytotoxicity o sensitization, o irritation; o pyrogenicity, and o 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 reprocessed Medline ReNewal LigaSure Impact, Curved, Large Jaw, Open Sealer/Divider (LF1212A) is substantially equivalent to the predicate devices.

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Curved, Small Jaw Open Sealer/Divider (LF1212A) device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Curved, Small Jaw Open Sealer/Divider	Medline ReNewal Reprocessed LigaSure Curved, Small Jaw Open Sealer/Divider	Same device; different manufacturer
Predicate 510(k)	K152286	K162751	N/A
Model Numbers	LF1212A	LF1212A	N/A
Intended Use/Indications for Use[a]	The Covidien LigaSure Curved Small Jaw, Open Sealer/Divide model LF1212A is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2 – 3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.	The Medline ReNewal Reprocessed LigaSure Curved Small Jaw, Open Sealer/Divide model LF1212A is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and in such surgical specialties as urologic, thoracic, plastic and reconstructive. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis. The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2 – 3 mm away from unintended thermally-sensitive structures such as nerves and	Same

Table 1: Predicate and: Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider (LF1212A) device comparison chart (concluded).

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Impact Curved, Large Jaw Sealer/Divider	**Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider**	**Same device; different manufacturer**
Intended Use/Indications for Use (concluded)[a]	The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.	parathyroid glands. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.	Same
Power Platform	ForceTriad Electrosurgical Generator running software version 3.40 or higher.[b]	ForceTriad Electrosurgical Generator running software version 3.40 or higher.[b]	Same
Technological Characteristics	The LigaSure Impact Curved Large Jaw, Open Sealer/Divider uses bipolar energy to seal and divide vessels up to and including 7 mm in diameter.	The LigaSure Impact Curved Large Jaw, Open Sealer/Divider uses bipolar energy to seal and divide vessels up to and including 7 mm in diameter.	Same

[a] Intended Use and Indications for Use were the same category in the K1522864 predicate.
[b] ForceTriad generator was cleared under K070162: It will not be reprocessed, and it is not part of this submission.