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

July 20, 2016

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

Re: K160333
Trade/Device Name: Medline ReNewal Reprocessed LigaSure Blunt Tip Open Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: June 17, 2016
Received: June 20, 2016

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 yours,

Christopher J. Ronk -A

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 Included in Clearance:

Device Model	Device Name	Original Manufacturer
LF1623	LigaSure Blunt Tip Open Sealer/Divider (5 mm x 23 cm)	Covidien
LF1637	LigaSure Blunt Tip Laparoscopic Sealer/Divider (5 mm x 37 cm)	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)*
K160333

Device Name
Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider

Indications for Use *(Describe)*

The Medline ReNewal Reprocessed LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 such surgical specialities as urologic, vascular, thoracic and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.
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."

Reprocessed Single-Use Device Models Included in Clearance:

Device Model	Device Name	Original Manufacturer
LF1623	LigaSure Blunt Tip Open Sealer/Divider (5 mm x 23 cm)	Covidien
LF1637	LigaSure Blunt Tip Laparoscopic Sealer/Divider (5 mm x 37 cm)	Covidien

K160333

Traditional 510(k) Notification
Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Dividers

Summary K160333

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Director, Quality Assurance and Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medline.com
Prepared by	Stephanie Boyle Mays Regulatory Affairs Specialist, Regulatory Affairs P: 541-516-4205 F: 541-516-4180 E: smays@medline.com
Date Prepared	February 3, 2015
Device Names	Proprietary Name: Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider Common Name: Bipolar electrosurgical instrument
Classification	Electrosurgical cutting and coagulation device and accessories Product code: NUJ Class: Class II, non-exempt
Predicate Device	K142929 LigaSure Blunt Tip Sealer/Divider
Reference Device	K141153 LigaSure; Curved Small Jaw Sealer/Divider, 5mm Blunt Tip Sealer/Divider, Maryland Jaw One Step Sealer/Divider, curved
Device Models	LF1623 and LF1637
Device Description	The Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider (LF1623, LF1637) devices are sterile single-use, hand-held bipolar vessel sealing devices designed for use with Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles and lymphatics clamped between the jaws, grasping tissue and blunt dissection during open and minimally invasive general surgical procedures (as indicated) using radio frequency (RF) energy. A hand-actuated lever allows the user to open or close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position during vessel sealing and cutting. The proposed devices do not include software.
Intended Use	The Medline ReNewal Reprocessed LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 such surgical specialities as urologic, vascular, thoracic and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. 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 and reference devices. The proposed devices are reprocessed versions of the predicate and reference devices.

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 60601-1, IEC 60601-2-2, and IEC 60601-1-2;
	• simulated use;
	• device integrity;
	• blade trigger advance/return;
	• shaft knob rotation;
	• device recognition;
	• thermal analysis characterization;
	• handle locking;
	• burst pressure;
	• histopathology;
	• seal quality;
	• tissue sticking;.
	• cleaning;
	  • protein and carbohydrates;
	• biocompatibility;
	  • 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 and reference devices, Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Dividers (LF1623 and LF1637) are substantially equivalent to the predicate.

K160333

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider comparison chart.

Device Characteristics	Predicate	Proposed	Reference Device	Comparison
	Covidien LigaSure Blunt Tip Sealer/Divider	**Medline ReNewal LigaSure Blunt Tip Sealer/Divider**	**Covidien LigaSure 5-mm Blunt Tip Laparoscopic Sealer/Divider[a]**	**Same devices; different manufacturer**
Predicate 510(k)	K142929	K160333	K141153	N/A[b]
Model Numbers	LF1623	LF1623, LF1637	LF1637	N/A
Device Description	The Covidien LigaSure Blunt Tip Sealer/Divider (LF1623, LF1644) devices are sterile single-use, hand-held bipolar vessel sealing devices designed for use with Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundels and lymphatics clamped between the jaws, grasping tissue and blunt dissection during open and minimally invasive general surgical procedures (as indicated) using radio frequency (RF) energy. A hand-actuated lever allows the user to open or close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed	The Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider (LF1623, LF1637) devices are sterile single-use, hand-held bipolar vessel sealing device is designed for use with Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles and lymphatics clamped between the jaws, grasping tissue and blunt dissection during open and minimally invasive general surgical procedures (as indicate) using radio frequency (RF) energy. A hand-actuated lever allows the user to open or close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position	Same as predicate	• K142929 (predicate) and proposed devices include open and laparoscopic blunt tip sealer/dividers. • K141153 (reference) and proposed devices specify use of the ForceTriad energy system. The ForceTriad system is a Covidien electrosurgical generator that is included in the K142929 description.

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider comparison chart (continued).

Device Characteristics	Predicate	Proposed	Reference Device	Comparison
	Covidien LigaSure Blunt Tip Sealer/Divider	**Medline ReNewal LigaSure Blunt Tip Sealer/Divider**	**Covidien LigaSure 5-mm Blunt Tip Laparoscopic Sealer/Divider**	**Same devices; different manufacturer**
Device Description *(concluded)*	position during vessel sealing and cutting. The proposed devices do not include software.	during vessel sealing and cutting. The proposed devices do not include software.	*(as stated previously)*	• All devices are LigaSure blunt-tip sealer/dividers
Indications for Use (IFU)	The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 surgery specialties as urologic, vascular, thoracic and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.	The Medline ReNewal Reprocessed LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or 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 such surgical specialities as urologic, vascular, thoracic and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. .	Same as predicate	Indications for use for the K142929 predicate LigaSure Sealer/Divider and the proposed devices are the same. The IFU for K142929 includes both the LF1623 and LF1637 in the instructions that accompany the devices.

(continued)

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Blunt Tip Sealer/Divider comparison chart (concluded).

Device Characteristics	Predicate	Proposed	Reference Device	Comparison
	Covidien LigaSure Blunt Tip Sealer/Divider	**Medline ReNewal LigaSure Blunt Tip Sealer/Divider**	**Covidien LigaSure 5-mm Blunt Tip Laparoscopic Sealer/Divider**	**Same devices; different manufacturer**
Indications for Use (concluded)	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 procedure.	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.	*(as stated previously)*	*(as stated previously)*
Power Platform	ForceTriad SW v.3.60 or higher for LF1623 ForceTriad SW v. 3.50 or higher for LF1637[c]	ForceTriad SW v.3.60 or higher for LF1623 ForceTriad SW v. 3.50 or higher for LF 1637	ForceTriad SW v. 3.50 or higher for LF1637	Same
Technological Characteristics	The only differences between the predicate and subject devices are the length of the shaft. Note: predicate device for K142929 is reference device K141153	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate and reference devices. The proposed devices are a reprocessed version of the predicate and reference devices.	Same as predicate.	Same

[a] Only the LigaSure 5 mm Blunt Tip Sealer/Divider is included in this submission from reference device K141153. Medline ReNewal is not including the LigaSure Curved Small Jaw Sealer/Divider or the Maryland Jaw One Step Sealer/Dividers in this submission.
[b] N/A = not applicable.
[c] ForceTriad generator was cleared under K070162: It will not be reprocessed, and it is not part of this submission.