DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 2, 2016

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

Re: K153745
Trade/Device Name: Medline Renewal Reprocessed Ligasure Impact 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: April 7, 2016
Received: April 8, 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,

Jennifer R. Stevenson -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
LF4318	LigaSure Impact Curved, Large Jaw, Open Sealer/Divider	Covidien

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153745

Device Name
Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider (LF4318)

Indications for Use *(Describe)*

The reprocessed Medline ReNewal LigaSure Impact LF4318 Curved Large Jaw, Open Sealer/Divider is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LF4318 is intended to be used with the ForceTriad energy platform to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Impact 4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary K153745

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. 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 Technical Writer, Product Development P: 541-516-4205 F: 541-923-3375 E: smays@medline.com
Date Prepared	December 23, 2015
Device Names	Proprietary Name: Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider (LF4318) Common Name: Bipolar electrosurgical instrument
Classification	Electrosurgical cutting and coagulation device and accessories Product code: NUJ Class: Class II, non-exempt Classification Number: 21 CFR § 878.4400
Predicate Device	K123444 LigaSure Impact Curved, Large Jaw, Open Sealer/Divider LF4318
Device Description	The reprocessed Medline ReNewal LigaSure Impact, Curved, Large Jaw, Open Sealer/Divider (LF4318) is a sterile, single-use, hand-held bipolar electrosurgical instrument designed exclusively for use with the ForceTriad Energy Platform (cleared under K051644, K070162) to seal and divide vessels (including pulmonary) up to and including 7 mm in diameter, tissue bundles, and lymphatics during open general surgical procedures. The ForceTriad's' tissue-fusion (LigaSure) mode is designed to deliver precise energy to tissue for a controlled time period to achieve complete and permanent tissue fusion. The device combines the benefits of a long, curved jaw and a shaft-based jaw mechanism for improved access and visibility to critical structures. The pistol-grip-style handle was designed for improved comfort and usability, with an integrated hand switch and cutter for the subsequent sealing and dividing of tissue. Hand controls have been symmetrically placed to facilitate handling by both left- and right-handed users. The LF4318 device connects to the ForceTriad energy platform with a 10-foot cord containing a LigaSure cable connector. This connector functions as a unique product identifier for device –specific recognition by the generator. The 10-foot cord, cable connector, and ForceTriad are not reprocessed by Medline ReNewal.

Intended Use	The reprocessed Medline ReNewal LigaSure Impact LF4318 Curved Large Jaw, Open Sealer/Divider is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LF4318 is intended to be used with the ForceTriad energy platform to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Impact 4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles. 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. K123444 LigaSure Impact Curved, Large Jaw, Open Sealer/Divider LF4318 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 60601-1 and 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 devices, Medline ReNewal reprocessed Medline ReNewal LigaSure Impact, Curved, Large Jaw, Open Sealer/Divider (LF4318) is substantially equivalent to the predicate devices.

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider (LF4318) device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Impact Curved, Large Jaw Sealer/Divider	**Medline ReNewal LigaSure Impact Curved, Large Jaw Sealer/Divider**	**Same device; different manufacturer**
Predicate 510(k)	K123444	TBD	N/A
Model Numbers	LF4318	LF4318	N/A
Intended Use/Indications for Use[a]	The Covidien LigaSure Impact Curved Large Jaw, Open Sealer/Divider is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LF4318 is intended to be used with the ForceTriad energy platform to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Impact 4318 can be used on vessels (arteries veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.	The reprocessed Medline ReNewal LigaSure Impact Curved Large Jaw, Open Sealer/Divider is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LF4318 is intended to be used with the ForceTriad energy platform to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Impact 4318 can be used on vessels (arteries veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.	Same

Table 1: Predicate and Medline ReNewal Reprocessed LigaSure Impact Curved, Large Jaw Sealer/Divider (LF4318) device comparison chart (concluded).

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Impact Curved, Large Jaw Sealer/Divider	**Medline ReNewal 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.	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 3.50 or higher.[b]	ForceTriad Electrosurgical Generator running software version 3.50 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 K123444 predicate.
[b] ForceTriad generator was cleared under K070162: It will not be reprocessed, and it is not part of this submission.