October 31, 2018

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

Re: K182588
Trade/Device Name: Medline ReNewal Reprocessed LigaSure Maryland Jaw Sealer/Dividers
(Model # LF1723, LF 1737, and LF1744)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: September 18, 2018
Received: September 20, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Long H. Chen -S Digitally signed by Long H. Chen -S Date: 2018.10.31 17:43:50 -04'00' 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

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)*
K182588

Device Name
Medline ReNewal Reprocessed LigaSure Maryland Jaw Sealer/Dividers (LF1723, LF1737, LF1744)

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed LigaSure Maryland Jaw 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 specialties 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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Reprocessed Single-Use Device Model Included in Submission:

Device Model	Device Name	Original Manufacturer
LF1723	Maryland Jaw Sealer Divider (13-mm jaw and 5-mm diameter x 23-cm long shaft)	Covidien
LF1737	Maryland Jaw Sealer Divider (13-mm jaw and 5-mm diameter x 37-cm long shaft)	Covidien
LF1744	Maryland Jaw Sealer Divider (13-mm jaw and 5-mm diameter x 44-cm long shaft)	Covidien

K182588 510(k) 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	
Contact/ Prepared by	Stephanie Boyle Mays Senior Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • E: smays@medline.com	
Date Prepared	October 29 2018	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed LigaSure Maryland Jaw Sealer/Dividers models LF1723, LF1737, and LF1744
	Common or Usual Name	Bipolar electrosurgical instrument
	Regulatory Name/Reference	Electrosurgical cutting and coagulation device and accessories reprocessed, 21 CFR § 878.4400
	Regulatory Class	Class II
	Product Code	NUJ
	Panel	General & Plastic Surgery
Predicate Device	510(k) Number	K141153
	Proprietary or Trade Name	LigaSure Maryland Jaw One Step Sealer/Dividers models LF1723, LF1737, and LF1744
	Common or Usual Name	Bipolar electrosurgical instrument
	Regulatory Name/Reference	Electrosurgical cutting and coagulation device and accessories reprocessed, 21 CFR § 878.4400
	Regulatory Class	Class II
	Product Code	GEI
	Panel	General & Plastic Surgery
	Manufacturer	Covidien 5920 Longbow Dr., Boulder, CO 80301
Device Description	The Medline ReNewal Reprocessed LigaSure Maryland Jaw Sealer/Dividers (models LF1723, LF1737 and LF1744) are sterile, single-use, hand-held bipolar electrosurgical instruments designed for use with the Covidien electrosurgical generators to ligate (seal) and divide (cut) vessels, tissue bundles and lymphatics during open and minimally invasive general surgical procedures using radio frequency (RF) energy. A hand actuated mechanism allows the user to open and close the instrument jaws. When the instrument jaws are correctly placed over tissue or vessel to be sealed, the user operates a second control to initiate delivery of bipolar energy, which seals the tissue. When the sealing cycle is complete, the user operates a separate control to activate a knife, which divides the tissue along the seal line.	

	The generators are not reprocessed by Medline ReNewal.
Indications for use	The Medline ReNewal Reprocessed LigaSure Maryland Jaw 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 specialties 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 device. The proposed devices are a reprocessed version of the predicate devices. K141153 LigaSure Maryland Jaw Sealer/Divider 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; • burst pressure; • histopathology; • seal quality; • Cleaning: o protein, and o carbohydrates; • Biocompatibility: o cytotoxicity o sensitization, o irritation; o pyrogenicity, and o acute systemic toxicity; • performance qualification; • sterilization validation; and • product stability.

Summary Table: Predicate and Medline ReNewal Reprocessed LigaSure Maryland Jaw Open Sealer/Divider device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Maryland Jaw One Step Sealer/Divider	**Medline ReNewal LigaSure Maryland Jaw Sealer/Divider**	**As Stated**
510(k)	K141153	TBD	N/A
Model Numbers	LF1723, LF1737, and LF1744	LF1723, LF1737, and LF1744	Same
Common Name	Bipolar electrosurgical instrument	Bipolar electrosurgical instrument	Same
Regulation No.	21 CFR § 878.4400	21 CFR § 878.4400	Same
Regulatory Class	Class II	Class II	Same
Product Code	GEI	NUJ	As stated
Indications for Use	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 such surgical specialties 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.	The Medline ReNewal Reprocessed LigaSure Maryland Jaw 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 specialties 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.	Same

Device Characteristics	Predicate	Proposed	Comparison
	Covidien LigaSure Maryland Jaw One Step Sealer/Divider	**Medline ReNewal LigaSure Maryland Jaw Sealer/Divider**	**As stated**
Power Platform[a]	• LF1723 = ForceTriad SW v3.6 or higher. • LF1737 = VL FT10 GEN SW v1.0 or higher • LF1744 = VL LS10 GEN SW v1.0 or higher	• LF1723 = ForceTriad SW v3.6 or higher.[b] • LF1737 = VLFT10GEN SW v1.0 or higher • LF1744 = VLLS10GEN SW v1.0 or higher	Same
Technological Characteristics	The LigaSure Maryland Jaw One Step Sealer/Divider uses bipolar RF energy to seal and divide vessels up to and including 7 mm in diameter.	The LigaSure Maryland Jaw One Step Sealer/Divider uses bipolar RF energy to seal and divide vessels up to and including 7 mm in diameter.	Same
[a] ForceTriad generator was cleared under K070162; VL FT10 generator was cleared under K151649; and the VL LS10 generator was cleared under K143654. None of the generators will be reprocessed by Medline ReNewal. They are not a part of this submission.			
Conclusion	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed LigaSure Maryland Jaw Sealer/Divider models LF1723, LF1737, and LF1744 are substantially equivalent to the predicate devices.		