April 23, 2018

Stryker Sustainability Solutions
Mr. Scott English
Staff Regulatory Affairs Specialist
1810 W Drake Drive
Tempe, Arizona 85283

Re: K180499
Trade/Device Name: Reprocessed LigaSure Maryland Jaw Sealer/Divider (Model # LF1723, LF1737, LF1744)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: February 23, 2018
Received: February 26, 2018

Dear Mr. English:

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.

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.

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,

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

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)*
K180499

Device Name
Reprocessed LigaSure Maryland Jaw Sealer/Divider (LF1723, LF1737, LF1744)

Indications for Use *(Describe)*
The 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 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.

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Reprocessed Single-Use Device Models Included in Clearance

Device Model	Device Name	Original Manufacturer
LF1723	LigaSure Maryland Jaw Sealer/Divider, 23cm Length	Covidien
LF1737	LigaSure Maryland Jaw Sealer/Divider, 37cm Length	Covidien
LF1744	LigaSure Maryland Jaw Sealer/Divider, 44cm Length	Covidien

510(k) SUMMARY

Submitter:
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Contact:
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Date of Preparation: April 17, 2018

Name of Device:

Trade/Proprietary Name: Reprocessed LigaSure Maryland Jaw Sealer/Divider (LF1723, LF1737, LF1744)

Common Name: Bipolar Electrosurgical Instrument

Classification Information: Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed
(21 CFR§878.4400, Product Code NUJ, Class II)

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
LF1723 LF1737 LF1744	K133338	LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series)	Covidien

Device Description:
The Covidien™ LigaSure™ 5 mm Maryland Jaw Sealer/Divider (LF1723, LF1737, LF1744) 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 instrument is intended to be used with Covidien electrosurgical generators that include vessel sealing capability. The instrument can be used on vessels (arteries and veins) up to and including 7 mm. The instrument creates a seal by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue. The outer diameter of the instrument shaft is 5 mm with a working length of 23 cm, 37 cm, or 44 cm. The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws and activating RF energy. The mechanism must be held in the closed position during vessel sealing and cutting.
- An activation button at the bottom of the handle for generator power to initiate vessel sealing.
- A trigger for actuating the cutter. The cutter can only be actuated when the jaws are closed.
- A rotation wheel to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator. The instrument attaches to the generator via a cable with a connector that identifies the instrument type to the generator.

The instrument is compatible with the Covidien™ ForceTriad™ Energy Platform and Valleylab™ FT10 Energy Platform.

The scope of this submission only includes the reprocessed Covidien sealer/divider device and not the ForceTriad Energy Platform or Valleylab FT10 Energy Platform that are used to power the device, or the footswitch that connects to the generator. Stryker Sustainability Solutions does not reprocess or market the generators or footswitch.

Intended Use:

The 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 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.

Summary of Technological Characteristics:

Reprocessed LigaSure Maryland Jaw Sealer/Dividers work in conjunction with Covidien electrosurgical generators. They use bipolar radiofrequency energy to seal tissues, blood vessels, and lymphatics. The devices also use mechanical action to divide tissue along the seal line. The design, materials, and intended use of the reprocessed device are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and size is utilized. The differences between the predicate device and the reprocessed device include the substitution of some components with new components. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of the LigaSure Maryland Jaw Sealer/Dividers includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed LigaSure Maryland Jaw Sealer/Divider. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Packaging Validation

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 and IEC 60601-2-18, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up to 7mm, including: burst pressure, maximum jaw temperature, device functionality, device reliability, and generator compatibility.

Additionally, preclinical laboratory evaluations in an animal model were performed, which included acute and chronic survival studies. The studies were done to evaluate thermal spread and the ability to achieve hemostasis of vessels of the reprocessed device. The results of the evaluations demonstrate that the Reprocessed LigaSure Maryland Jaw Sealer/Divider effectively cut and coagulated vessels up to and including 7mm in diameter.

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

Conclusion:

The results of bench testing and preclinical laboratory evaluations demonstrate that the Reprocessed LigaSure Maryland Jaw Sealer/Dividers are at least as safe and effective and perform as well as the identified legally marketed predicate device as described herein.