May 25, 2022

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

Re: K220481
Trade/Device Name: Remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 21, 2022
Received: April 25, 2022

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220481

Device Name
Remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019)

Indications for Use *(Describe)*
The Remanufactured LigaSure Sealer/Divider 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. Procedure 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)

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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510(k) SUMMARY

Submitter:
Stryker Sustainability Solutions
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Tempe, Arizona 85283

Contact:
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Principal Regulatory Affairs Specialist
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Date of Preparation: May 24, 2022

Name of Device:

Trade/Proprietary Name: Remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019)

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification Information: Electrosurgical, Cutting & Coagulation Accessories (21 CFR§878.4400, Product Code GEI, Class II)

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
LF2019	K173281	LigaSure Exact Dissector, Nano-coated	Covidien

Device Description:

The Remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019) 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 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 following controls are located on the device:

- Scissor like design 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. The button has two stages that provide tactile feedback to the user. The first stage

button click does not apply energy, whereas the second stage click begins energy application.
- A trigger for actuating the blade.

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 attached to the generator via a cable with a connector that identifies the instrument type to the generator.

For the LF2019, the Original Manufacturer applies a non-stick coating the jaws of the device to reduce tissue sticking. When remanufacturing the LF2019, Stryker Sustainability Solutions will not apply a non-stick coating to the jaws of the device.

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

The scope of the submission only includes the Remanufactured LigaSure Exact Dissector, Without Nano-coating and not the Valleylab FT10 Energy Platform that is used to power the device, or the footswitch that connects to the generator. Stryker Sustainability Solutions does not reprocess, remanufacture, or market the generators or footswitch.

Intended Use:

The Remanufactured LigaSure Sealer/Divider 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. Procedure 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.

Indications for Use Comparison:

The indications for use for the proposed device are the same in comparison to the predicate device.

Technological Comparison:

The design, materials, and intended use of the Remanufactured LigaSure Exact Dissector, Without Nano-coating are equivalent to the predicate device. The mechanism of action of the remanufactured device is identical to the predicate device in that the same standard mechanical design, materials, and size is utilized. There are no changes to the claims, intended use, clinical application, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' remanufacturing of the device 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. The only differences between the Remanufactured LigaSure Exact Dissector, Without Nano-coating and the predicate LigaSure Exact Dissector, Nano-coated are that the device is remanufactured, and some device components are replaced with equivalent components during the remanufacturing operation. The nano-coating is not replaced during the remanufacturing operation.

	Predicate Device	Subject Device
Uses	Single Patient Use	Single Patient Use
Device Length	21cm	21cm
Jaw Length	20.6mm	20.6mm
Jaw Shape	Curved	Curved
Mechanism for Cutting	Mechanical – User actuated blade	Mechanical – User actuated blade

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Remanufactured LigaSure Exact Dissector, Without Nano-coating. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization
- Electrical Safety and Electromagnetic Compatibility
- Functional Performance Tests
  - Blade Trigger Actuation Force
  - Clamp Arm Closing and Seal Button Force
  - Clamp Arm Opening Force
  - Clamp Arm Deflection
  - Jaw Clamp Force
  - Blade Excursion
  - Jaw Opening Angle
  - Burst Pressure
  - Maximum Jaw Temperature
  - Device Reliability
  - Functional Attribute Testing

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 verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels from 1mm to 7mm, including burst pressure, maximum jaw temperature, device functionality, device reliability, and functional attribute tests.

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 remanufactured device.

Conclusion:

The results of bench testing and preclinical laboratory evaluations demonstrate that the Remanufactured LigaSure Exact Dissector, Without Nano-coating is at least as safe and

effective as the predicate and perform as well as the identified legally marketed predicate device as described herein.