March 23, 2021

Covidien
Nancy Sauer
Director, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K202917
Trade/Device Name: LigaSure Exact Dissector, Nano-coated
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 22, 2021
Received: February 24, 2021

Dear Nancy Sauer:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202917

Device Name
LigaSure™ Exact Dissector, Nano-coated

Indications for Use *(Describe)*
The 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. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, breast procedures, 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

Date summary prepared: February 17, 2021

**510(k) Submitter/Holder**
Covidien
5920 Longbow Drive
Boulder, CO 80301

**Contact**
Nancy Sauer
Director, Regulatory Affairs
Telephone: 720-361-5290
Fax: 303-530-6313
Email: nancy.k.sauer@medtronic.com

**Name of Device**

| | |
|---|---|
| Trade Name: | LigaSure™ Exact Dissector, Nano-coated |
| Catalog Numbers: | LF2019 |
| Common Name: | Bipolar Vessel Sealing Device |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI) |

**Predicate Device**

| | |
|---|---|
| Trade Name: | LigaSure™ Exact Dissector, Nano-coated |
| Catalog Numbers: | LF2019 |
| Common Name: | Bipolar Vessel Sealing Device |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI) |
| 510(k) Number: | K173281 |
| Manufacturer: | Covidien |

**Reference Device**

| | |
|---|---|
| Trade Name: | LigaSure™ Curved, Small Jaw, Open Sealer/Divider |
| Catalog Number: | LF1212/ LF1212A |
| Common Name: | Bipolar Vessel Sealing Device |
| Classification Name: | Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI) |
| 510(k) Number: | K152286 |
| Manufacturer: | Covidien |

**Device Description**
The LigaSure™ Exact Dissector, Nano-coated (LF2019) device is a sterile, single-use, coated, hand-held bipolar vessel sealing devices designed for use with compatible Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasp tissue, and perform blunt dissection during general surgical procedures (as indicated) using radio frequency (RF) energy.

A hemostat style body allows the user to open or close the instrument jaws during vessel sealing and cutting, with a single activation button incorporated into the body of the device.

**How Provided**
The LigaSure™ Exact Dissector, Nano-coated (LF2019) device is provided sterile and is intended for single use.

**Compatible Electrosurgical Generators:**
- ForceTriad™ Energy Platform (ForceTriad)
- Valleylab™ LS10 Generator (VLLS10GEN)
- Valleylab™ FT10 Energy Platform (VLF10GEN)

**Indications for Use**
The 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. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, breast procedures, 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.

**Patient Contacting Materials**
Twenty-seven parts were determined to come into direct contact with the patient or user. The materials that comprise these parts, their location within the proposed (LF2019) device, and full biocompatibility information were identified in the original premarket submission for the LF2019 device (K173281).

**Comparison of Technological Characteristics with the Predicate Device**
The LigaSure™ Exact Dissector, Nano-coated (LF2019) device is unchanged from the predicate device, as cleared under K173281, in terms of intended use, design, performance and technological characteristics. The only difference is that the indications for use have been updated to include breast procedures.

| Characteristic | Subject Device<br>LigaSure™ Exact Dissector, Nano-coated (LF2019) | Predicate Device<br>LigaSure™ Exact Dissector, Nano-coated (LF2019) [K173281] | Results (compared to predicate) |
|---|---|---|---|
| **Classification Regulation** | 878.4400 | 878.4400 | Same |
| **Class** | II | II | Same |
| **Product Code** | GEI | GEI | Same |
| **Indications for Use** | The 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. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, breast procedures, and adhesiolysis.<br><br>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.<br><br>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 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. Procedures may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication and adhesiolysis.<br><br>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.<br><br>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. | Addition of surgical specialties and procedures, same intended use |
| **Contraindications** | None | None | Same |
| **Maximum Vessel Diameter** | 7 mm | 7 mm | Same |
| **Single Use** | Yes | Yes | Same |
| **Sterile** | Yes | Yes | Same |
| **Sterilization Method** | EtO | EtO | Same |
| **Packaging** | HDPE die cut card in a Tyvek/Nylon pouch | HDPE die cut card in a Tyvek/Nylon pouch | Same |
| **Energy Type** | Electrical (RF) bipolar energy | Electrical (RF) bipolar energy | Same |
| **Compatible Energy Platform*** | ForceTriad energy platform (K110268)<br>Valleylab™ LS10 (K143654)<br>Valleylab™ FT10 (K191601) | ForceTriad energy platform (K110268)<br>Valleylab™ LS10 (K143654)<br>Valleylab™ FT10 (K191601) | Same |
| **Energy Activation** | Handswitch or footswitch | Handswitch or footswitch | Same |
| **Hand-activated Button Design** | Two-stage | Two-stage | Same |
| **Proprietary Connector** | Yes | Yes | Same |
| **Corded** | Yes | Yes | Same |
| **Jaw Type** | Bilateral | Bilateral | Same |
| **Jaw Shape** | Curved | Curved | Same |
| **Instrument Design** | Hemostat style | Hemostat style | Same |

**Performance Data**
No design or specification changes are associated with the expanded indication of the LigaSure™ Exact Dissector, Nano-coated (LF2019) device. Evidence of safety and effectiveness was presented in the previously submitted 510(k) and includes the following:

- Testing in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2
- Biocompatibility (ISO 10993-1)
- Device functionality
- Bench burst pressure
- *In vivo* acute and chronic animal studies

**Relevance of Reference Predicate Device**
The LF1212A LigaSure™ Curved, Small Jaw Open Vessel Sealer/Divider is used as a reference device in this submission. This is a valid reference device because it is used for the same intended use as the subject device and it uses the same principle of operation. It is very similar to the LigaSure™ Exact in terms of design and materials. It served as the predicate device for the initial clearance of the LigaSure Exact in premarket notification K173281.

The purpose of the reference device in this submission is to provide reference data for hemostasis performance and thermal spread in a LigaSure™ device for which there is a substantial body of literature showing successful use in breast procedures. The performance comparison between the LigaSure™ Exact and the LigaSure™ Curved Small Jaw supports the conclusion that the published data can be extrapolated to the LigaSure™ Exact device.

**Clinical Literature Summary**
A study of literature for breast procedures performed using LigaSure™ devices show that the hemostat-style open LigaSure™ devices have been used successfully in breast procedures including mastectomy, flap reconstruction, and axillary lymph node dissection. The safety and effectiveness outcomes reported in the literature were associated with effective hemostasis, operative time, blood, thermal damage, and intraoperative and postoperative complications, the same types of outcomes that are reported for other surgical procedures carried out with LigaSure™ devices. There are no new risk concerns for the LigaSure™ Exact Dissector, Nano-coated (LF2019) device when used to perform these procedure types. LigaSure™ technology performed well in the published studies.

**Conclusions**
The proposed LigaSure™ Exact Dissector, Nano-coated (LF2019) device for use in breast surgical procedures is substantially equivalent to the predicate LigaSure™ Exact Dissector, Nano-coated (LF2019) for its indicated use in general surgery and in such surgical specialties as urologic, thoracic, plastic, and reconstructive. The previously conducted bench and animal studies and clinical literature discussed in this submission have demonstrated that the device is suitable for the proposed expanded indications and that no new safety issues are identified with these indications.