DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 21, 2017

Covidien
Mr. Celso Duran
Senior Specialist, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K170869
Trade/Device Name: LigaSure Maryland Jaw Sealer/Divider One-step Sealing, 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: March 22, 2017
Received: March 23, 2017

Dear Mr. Duran:

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,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
LigaSure™ Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated

Indications for Use *(Describe)*
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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date summary prepared: 4/21/2017

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

Celso Duran
Senior Specialist, Regulatory Affairs
Telephone: 303-530-6445
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Name of Device

Trade Name:	LigaSure™ Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated
Catalog Numbers:	LF1923, LF1937, LF1944
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™ Maryland Jaw Sealer/Divider One-step Sealing
Catalog Numbers:	LF1723, LF1737, LF1744
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:	K133338 (cleared 12/20/2013), K141153 (cleared 8/14/2014)
Manufacturer:	Covidien

Reference Devices

Trade Name:	LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated
Catalog Number:	LF4418
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:	K162047
Manufacturer:	Covidien

Trade Name:	LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider
Catalog Number:	LF5637 and LF5644
Common Name:	Bipolar and Monopolar Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)
510(k) Number:	K161804
Manufacturer:	Covidien

Device Description
The LigaSure™ Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated (LF19XX) devices are sterile, single-use, coated, hand-held bipolar vessel sealing devices designed for use with 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 hand actuated lever 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 handle. The proposed devices come in three shaft lengths (23, 37, and 44 cm) and do not contain software.

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.

Comparison of Technological Characteristics with the Predicate Device
The application of radio frequency (RF) energy to target tissue is the fundamental technology for both the subject and predicate devices. A seal is created by application of RF energy to structures (vasculature, lymphatics, and tissue bundles) interposed between the jaws of the instrument. A blade within the instrument is user actuated to divide tissue after the seal is created. At a high level, the subject and predicate devices are based on the following same technological elements:

- Unilateral jaws – used to reach target structures (vasculature, lymphatics, and tissue bundles)
- Lever –closes the jaws to grasp the tissue
- Activation button – in-line mechanism allows RF energy to be activated by the user
- Cutting trigger – allows user to divide (cut) sealed structures

The only differences between the subject and predicate devices are the addition of a non-stick coating to the jaws of the proposed devices and minor manufacturing changes.

Performance Data
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
The biocompatibility evaluation for the LigaSure™ Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated devices was conducted in accordance with International Standard ISO 10993-1 “Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process,” as recognized by FDA. The battery of testing included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Materials Mediated Pyrogenicity

- Hemolysis

Electrical Safety and Electromagnetic Compatibility (EMC)
The system complies with relevant clauses of the ANSI AAMI ES 60601-1 and IEC 60601-2-2 standards for electrical safety and IEC 60601-1-2 standard for EMC.

Mechanical/Functional Testing
Mechanical, electrical, and functional testing was carried out to verify that the proposed devices performed as expected.

- Jaw force
- Jaw gap
- Device resistance, capacitance, and inductance
- Jaw Hyper-Extension
- Reliability Use Case Test

***Ex-vivo* Vessel Burst Pressure**
Ex-vivo burst pressure testing of excised fresh porcine renal arteries and lymphatics was conducted on both the subject and predicate devices to demonstrate bipolar electrosurgical vessel sealing performance.

Acute Animal Study
In the animal study conducted, porcine underwent various procedures to assess acute sealing performance and lateral thermal damage by the subject and predicate devices. The thermal safety of the new device was evaluated. These studies demonstrated that the subject devices are as safe and effective as the predicate devices.

Chronic Animal Study
A chronic study was conducted to assess seal quality over the course of 21 days. All animals survived 21 days post-op and all seals maintained chronic hemostasis.

Clinical Studies
This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Summary
Based on the preclinical performance as documented in the performance testing, the LigaSure™ Maryland Sealer/Divider One-step Sealing, Nano-coated devices were found to have a safety and effectiveness profile that is similar to the predicate devices.

Conclusions
The subject devices have the same indications for use as the legally marketed predicate devices. Furthermore, design changes made to introduce the subject devices do not raise different kinds of safety and effectiveness questions. Verification and validation data support substantial equivalence of the modified LigaSure™ Maryland Sealer/Divider Once-step Sealing, Nano-coated devices to the legally marketed predicate devices.