DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 16, 2016

Covidien
Ms. Dawn D. Tindall
Senior Regulatory Affairs Product Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K161804
Trade/Device Name: LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider (LF5637, LF5644)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 1, 2016
Received: September 2, 2016

Dear Ms. Tindall:

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 Part 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 Parts 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 yours,

Christopher J. Ronk -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)*
K161804

Device Name
LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider (LF5637, LF5644)

Indications for Use *(Describe)*
The LigaSure Retractable L-Hook Laparoscopic Sealer/Divider is a 5mm bipolar/monopolar electrosurgical instrument intended for use in minimally invasive 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 7mm in diameter. The monopolar L-Hook can be used to dissect through tissue planes and to create enterotomies or gastrotomies.

It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, colorectal, bariatric, and gynecologic. Procedures may include, but are not limited to, gastric bypass, hysterectomy, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, 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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510(k) Summary
Date summary prepared: June 28, 2016

510(k) Submitter/Holder
Covidien
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Name of Device

Trade Name:	LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider
Catalog Numbers:	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)

Predicate Devices:	Primary
Trade Name:	LigaSure™ Advance Monopolar Tip Sealer/Divider, Pistol Grip
Common Name:	Bipolar and Monopolar Electrosurgical Instrument
Catalog Number:	LF5544
510(k) Number:	K150835 (cleared 10/15/15); K063195 (clearance 11/29/06)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall
	Secondary
Trade Name:	LigaSure™ 5mm Maryland Jaw Sealer/Divider
Common Name:	Bipolar and Monopolar Electrosurgical Instrument
Catalog Number:	LF1723, LF1737, LF1744
510(k) Number:	K141153 (cleared 08/14/14); K133338 (cleared 12/20/13)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall
	Secondary
Trade Name:	Valleylab Laparoscopic Handswitch/Electrodes
Common Name:	Monopolar Electrodes
Catalog Number:	E2773-36
510(k) Number:	K904560 (cleared 12/31/1990)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall

No reference devices were used in this submission.

Device Description
The LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider is a 5mm sterile, single-use, hand-held bipolar electrosurgical instrument designed for use with compatible Covidien generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics during general procedures (as indicated) and monopolar capabilities to electrically dissect through tissue planes and to create openings in bowel (enterotomies) and stomach (gastrotomies). Covidien electrosurgical generators that include vessel sealing capabilities deliver precise energy through the device to tissue for a controlled tissue response to achieve complete and permanent tissue fusion while producing minimal sticking, charring, and thermal spread to adjacent tissue. The new device will be provided EO sterilized with a 5mm diameter shaft, in shaft lengths of 37 cm and 44 cm with a fine curved jaw featuring an extendable and retractable monopolar L-Hook. The proposed devices do not contain software.

Indications for use:
The LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider is a 5mm bipolar/monopolar electrosurgical instrument intended for use in minimally invasive 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 7mm in diameter. The monopolar L-Hook can be used to dissect through tissue planes and to create enterotomies or gastrotomies.

It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, colorectal, bariatric, and gynecologic. Procedures may include, but are not limited to gastric bypass, hysterectomy, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, 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 subject device and the predicate devices are based on the following same technological elements:

- LigaSure Advance Bipolar
  - Electrical RF Bipolar Energy
  - Pistol grip and momentary pistol trigger
  - Integrated and independent cutting blade
  - Sterilized, Single use
  - Intended use for Advance Bipolar
  - Generator Compatibility
- Monopolar
  - Monopolar Energy
  - Monopolar electrode
  - Sterilized, single use
  - Intended use for monopolar
  - Generator Compatibility

The following technological differences exist between the subject and predicate devices:

- Mechanical Deployment/Retraction Feature

- Monopolar Electrode Shape
- Monopolar Power Settings
- Monopolar Operating Voltage
- Inline Energy Activation
- Shaft/Jaw Rotation

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

Biocompatibility
The biocompatibility evaluation for the LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider devices was conducted in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process". The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemolysis

The direct patient-contacting materials are: stainless steel, ceramic, and polymers including ETFE, PTFE, fiberglass, polyamide, polyester, polypthalamide, and HDPE.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety testing and EMC testing were conducted on the LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider devices. The system complies with relevant portions of the IEC 60601-1, IEC 60601-2-2, and IEC 60601-2-18 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 new devices perform as expected and conform to requirements defined in related design inputs and subsequent product specifications.

LigaSure Advanced Bipolar

Ex-vivo Renal Burst Pressure
Ex-vivo burst pressure testing of excised fresh porcine renal arteries was conducted using the LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider devices in comparison to the Maryland LF17XX predicate device. Testing utilized the ForceTriad and the FT10 generators.

Ex-Vivo / Lymphatic
A pre-clinical study using a porcine model was conducted to evaluate the lymphatic duct sealing performance of the LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider devices in comparison to the predicate Maryland LF17XX devices. Testing utilized the ForceTriad and the FT10 generators.

In-Vivo Acute
A pre-clinical study using a porcine model was conducted to verify acute hemostasis and lateral thermal spread with the subject devices and the predicate Maryland LF17XX device. Testing utilized the ForceTriad and the FT10 generators.

Monopolar

Ex-vivo Monopolar Thermal Effect
Monopolar *ex-vivo* testing evaluated thermal effect resulting from monopolar energy application across the range of power setting and modes on LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider (LF5637/LF5644) devices in comparison to the predicate laparoscopic L-Hook (E2773-36) attached to a Force TriVerse (FT3000) pencil. Testing utilized the ForceTriad and the FT10 generators. Monopolar thermal effects were evaluated on three different tissue types with three power settings for all three energy modes.

In-Vivo Acute
Enterotomy formation was verified with the subject device and the predicate controls of LF5544 and L-hook E2773-36 in a pre-clinical study using a porcine model. Testing utilized the ForceTriad and the FT10 generators

Chronic Animal Study
A Chronic Hemostasis Porcine study was conducted to verify the performance of the LigaSure™ Retractable L-Hook Laparoscopic Sealer Divider devices on the ForceTriad™ and FT10™ generators when used on vessels 7mm or smaller and tissue bundles during general surgical procedures.

Human Factors and Usability
The usability engineering process applied to these devices was in compliance with the requirements of IEC 62366 "Medical devices—Application of usability engineering to medical devices". The process included analysis of user needs and potential use errors followed by testing to demonstrate that representative users can use the instruments safely and effectively.

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

Summary
Based on the pre-clinical performance as documented in the performance testing, the LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider was found to have a safety and effectiveness profile that is similar to the predicate devices.

Conclusions
The comparison of device characteristics and the review of the performance data support the conclusion that the LigaSure™ Retractable L-Hook Laparoscopic Sealer/Divider devices are substantially equivalent to the predicate devices. The devices have the same intended use for their common fundamental technologies. The proposed device has some intentional design differences that enable it to be well suited for its indicated uses. Testing has demonstrated that these differences do not raise any new questions of safety or effectiveness.