



Food and Drug Administration
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September 15, 2016

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

Re: K162047

Trade/Device Name: LigaSure Impact Curved, Large Jaw, Open Sealer/divider, 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: August 31, 2016

Received: September 1, 2016

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 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,

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K162047

Device Name

LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, 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, veins, pulmonary arteries, pulmonary 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.

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510(k) Summary

Date summary prepared: 8/17/2016

510(k) Submitter/Holder

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Contact

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Name of Device

Trade Name: LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated
Catalog Numbers: LF4418
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 Impact™ Curved, Large Jaw, Open Sealer/Divider
Catalog Number: LF4318
Common Name: Bipolar Vessel Sealing Device
510(k) Number: K123444 (cleared 1/30/2013), K141153 (cleared 8/14/2014)
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 Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated (LF4418) is a sterile, single-use, coated, hand-held bipolar vessel sealing device designed for use with Covidien electrosurgical generators that include vessel sealing capabilities to ligate (seal) and divide (cut) vessels, tissue bundles, pulmonary arteries/veins, and lymphatics during open general surgical procedures (as indicated). A hand actuated lever allows the user to open or close the instrument jaws, and includes a latching mechanism that holds the jaws in the closed position during vessel sealing and cutting. The proposed devices do not contain software.

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, veins, pulmonary arteries, pulmonary 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.

Special 510(k): LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated (LF4418)

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 is the principle for both the subject and predicate devices. A seal is created by application of RF energy to structures (vascular and lymphatics) 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:

- Bilateral jaws – used to reach target structures (vascular and lymphatics)
- Lever – incorporates a latch mechanism to hold the jaws in the closed position
- Activation button – allows RF energy to be activated by the user
- Cutting trigger – allows user to divide (cut) sealed structures

The only difference between the subject and predicate devices is the addition of a non-stick coating to the jaws of the proposed device.

Performance Data

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

Biocompatibility

The biocompatibility evaluation for the LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated device 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 tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemolysis

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing and EMC testing was conducted on the LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated device. 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 device performed as expected.

- Jaw force
- Jaw gap
- Shaft/Jaw Rotation
- Device resistance, capacitance, and inductance
- Lever latching/unlatching/opening force

Ex-vivo Vessel Burst Pressure

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

Thermal Profile

Bench thermal profile testing using porcine tissue was conducted to evaluate the thermal profile of the jaw and shaft of the subject device in comparison to the predicate.

Acute Animal Study

In the animal study conducted, two female 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 by macroscopic and histological evaluation of the tissue that was sealed and divided. These studies demonstrated that the subject devices are as safe and effective as the predicate device.

Chronic Animal Study

A chronic study on five animals to assess seal quality over the course of 21 days was conducted. 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 Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated device was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The subject device has the same indications for use as the legally marketed predicate device. Furthermore, design change made to introduce the coated device does not raise different kinds of safety and effectiveness questions. Verification and validation data support substantial equivalence of the modified LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider, Nano-coated devices to the legally marketed predicate device.