



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

August 12, 2016

Covidien  
Mr. Hong Zhu  
Regulatory Affairs Manager  
6F, Building 3, 2388 Chenhong Road, Minhang District  
Shanghai, 201114 China

Re: K160331

Trade/Device Name: Ligasure Curved Jaw, Open Sealer/Divider Electrode (LF3225),  
Ligasure Curved Jaw Open Reusable Clamp (LF3225C)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: July 5, 2016

Received: July 15, 2016

Dear Mr. Zhu:

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 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

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

### Indications for Use

510(k) Number (if known)  
K160331

Device Name  
LigaSure™ Curved Jaw, Open Sealer/Divider Electrode (LF3225)

Indications for Use (Describe)

The LigaSure Sealer/Divider, comprised of a single use electrode and a reusable clamp, is intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.

The LigaSure Electrode is a single use component that attaches to the LigaSure Clamp. After assembly, 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, reconstructive, and gynecologic . Procedures may include, but are not limited to, bowel resections, hysterectomy, oophorectomy , gall bladder procedures, Nissen fundoplication, and adhesiolysis.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
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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."*

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)  
K160331

Device Name  
LigaSure™ Curved Jaw, Open Reusable Clamp (LF3225C)

### Indications for Use (Describe)

The LigaSure Sealer/Divider, comprised of a single use electrode and a reusable clamp, is intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.

The LigaSure Clamp is a reusable handpiece to which the LigaSure Electrode attaches. Refer to the labeling of the compatible electrode for specific indications.

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: August 11, 2016

**510(k) Submitter/Holder**

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**Contact**

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**Name of Device**

Trade Name: LigaSure™ Curved Jaw, Open Sealer/Divider  
Catalog Numbers: LF3225, LF3225C  
Common Name: Bipolar electrosurgical vessel sealing device  
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI).

**Predicate Devices**

The LigaSure™ Curved Jaw Open Sealer/Divider (LF3225, LF3225C) was compared to and found to be substantially equivalent to the following legally marketed products.

*Primary*

Trade Name: LigaSure™ Standard Instrument  
Common Name: Bipolar Vessel Sealing Device  
Catalog Number: LS2070, LS2071  
510(k) Number: K043273 (cleared 01/05/2005), K981916 (cleared 08/28/1998)  
Manufacturer: Covidien  
Recall: This device has not been subject to a design-related recall.

The LigaSure™ Standard Instrument is a part of LigaSure™ Vessel Sealing System.

*Secondary*

Trade Name: LigaSure™ Curved, Small Jaw, Open Sealer/Divider  
Common Name: Bipolar Vessel Sealing Device  
Catalog Number: LF1212A  
510(k) Number: K152286 (cleared 09/08/2015), K141153 (cleared 8/14/2014), K113572 (cleared 9/5/2012), K102470 (cleared 2/7/2011)  
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™ Curved Jaw, Open Sealer/Divider (LF3225, LF3225C) is a hand-held bipolar electro-surgical vessel sealing device intended for use with compatible Covidien generators that include LigaSure™ vessel sealing capabilities to ligate (seal) and divide (cut) blood vessels, tissue bundles, and lymphatics during open general surgical procedures (as indicated). It is composed of a reusable hemostat-style clamp and a sterile single-use electrode.

The device creates a seal by application of RF electro-surgical energy delivered from the compatible Covidien generators to vascular structures (vessels and lymph) or tissue bundles interposed between the jaws of the instrument. Covidien electro-surgical generators that include vessel sealing capabilities deliver precise energy through the instrument 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. Once the seal cycle is complete, surgeon actuates a blade within the electrode of the instrument to divide the tissue along the seal line. The proposed device does not contain software.

## Indications for Use

### *LigaSure™ Curved Jaw, Open Sealer/Divider Electrode (LF3225)*

The LigaSure Sealer/Divider, comprised of a single use electrode and a reusable clamp, is intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.

The LigaSure Electrode is a single use component that attaches to the LigaSure Clamp. After assembly, 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, reconstructive, and gynecologic. Procedures may include, but are not limited to, bowel resections, hysterectomy, oophorectomy, gall bladder procedures, Nissen fundoplication, and adhesiolysis.

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.

### *LigaSure™ Curved Jaw Open Reusable Clamp (LF3225C)*

The LigaSure Sealer/Divider, comprised of a single use electrode and a reusable clamp, is intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.

The LigaSure Clamp is a reusable handpiece to which the LigaSure Electrode attaches. Refer to the labeling of the compatible electrode for specific indications.

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 LigaSure™ Curved Jaw Open Sealer/Divider (LF3225, LF3225C) has the equivalent technological and performance characteristics as the predicates. This 510(k) proposes a combination of the technological characteristics from two predicates into a new device. The proposed device is similar to the LigaSure™ Standard Instrument that includes both a single-use disposable electrode and a reusable/resterilizable clamp. It also incorporates integrated blade and in-line activation features from the LigaSure™ Curved, Small Jaw device.

The assembled proposed device, similar to the LigaSure™ Standard Instrument, is comprised of a single-use disposable component (LigaSure™ Electrode) and a reusable/resterilizable component (LigaSure™ Clamp). The LigaSure™ Clamp is a hemostat-style device and is provided non-sterile. It can be steam sterilized and reused up to 200 cycles. The LigaSure™ Electrode is an EO sterilized single-use device. It's integrated with an in-line purple button (RF switch) that can be pressed by surgeons to seal vessels, tissue bundles or lymphatics. A blade contained in the electrode can be triggered by surgeons to divide the vessels after seal

cycle completes. The device is designed to be both ergonomic and intuitive for the user. Its hemostat-style body and symmetrically placed controls facilitate a single handling by either right or left-handed users.

LigaSure™ Curved Jaw Open Sealer/Divider (LF3225, LF3225C) can be used with Covidien compatible generators, specified in the Instructions for Use. When it is applied to a blood vessel, a lymphatic vessel, or tissue bundle, RF energy can be activated through an in-line purple button (RF switch) from the device or a footswitch connected to the generator.

## Performance

Verification and validation activities were successfully completed and establish that the LigaSure™ Curved Jaw, Open Sealer/Divider performs as intended and is substantially equivalent to its predicates. Evidence of safety and effectiveness in support of substantial equivalence was obtained from design verification testing, including the following bench and preclinical studies:

- Sterilization validation and shelf life study
- Biocompatibility evaluation in accordance with ISO 10993-1:2009
- Compliance with EMC and Electrical Safety Standards:
  - AAMI/AMSI ES 60601-1: 2005+A1: 2012
  - IEC 60601-2-2: 2009
  - IEC 60601-1-2: 2007
- Engineering and functional testing including system, mechanical, electrical and general functional testing
- *Ex vivo* and *in vivo* testing using porcine tissue and a porcine model showed comparable performance with regard to thermal effects and vessel sealing capabilities.

## Conclusion

Verification and validation testing demonstrates that the proposed LigaSure™ Curved Jaw, Open Sealer/Divider is substantially equivalent to the predicate devices: LigaSure™ Standard Instrument and LigaSure™ Curved, Small Jaw, Open Sealer/Divider. All devices have the same intended use and fundamental technology. The proposed device does not raise any new questions of safety and efficacy when compared with the predicates.