



Food and Drug Administration
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September 8, 2015

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

Re: K152286

Trade/Device Name: LigaSure™ Curved, Small Jaw, Open Sealer/Divider (LF1212A)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 11, 2015
Received: August 13, 2015

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 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" (21CFR 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,

David Krause -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

Indications for Use

510(k) Number (if known)

K152286

Device Name

LigaSure™ Curved, Small Jaw, Open Sealer/Divider (LF1212A)

Indications for Use (Describe)

The LF1212A 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.

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.

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510(k) Summary

Date summary prepared: August 11, 2015

510(k) Submitter/Holder

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Contact

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Name of Device

Trade Name: LigaSure™ Curved, Small Jaw, Open Sealer/Divider
Catalog Numbers: LF1212A
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™ Curved, Small Jaw, Open Sealer/Divider
Common Name: Bipolar Vessel Sealing Device
Catalog Number: LF1212A
510(k) Number: 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, Small Jaw, Open Sealer/Divider (LF1212A) is a 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 open general surgical procedures (as indicated). 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 surgeon first grasps the vessel or tissue with the jaws of the instrument. Once the surgeon is confident that the instrument is placed correctly, he or she initiates a seal by pressing a handswitch or footswitch. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) or tissue bundles interposed between the jaws of the instrument. Once the seal cycle is complete, the surgeon actuates a blade within the instrument to divide tissue along the seal line.

The purpose of this submission is to propose the use of an alternate dot material for the LigaSure Curved, Small Jaw, Open Sealer/Divider devices (K141153). There have been no prior submissions for the proposed change. The proposed devices do not contain software.

Indications for Use

The LF1212A 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.

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.

Comparison of Technological Characteristics with the Predicate Device

The LigaSure™ Curved, Small Jaw, Open Sealer/Divider devices have the same technological and performance characteristics as the predicate. This Special 510(k) proposes changes to the material of the ceramic spacers on the jaws of the device. The addition of an etched wetting ring feature is also included. The function of the device has not changed.

Performance Data

The modification to the LigaSure™ Curved, Small Jaw, Open Sealer/Divider (LF1212A) device was found to not affect safety or performance through design verification testing which confirmed the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards, as follows:

- Biocompatibility evaluation in accordance with ISO 10993-1:2009
- Basic safety and essential performance in accordance with IEC 60601-1: 2005, A1: 2012 and IEC 60601-2-2: 2009
- Electromagnetic compatibility in accordance with IEC 60601-1-2: 2007, CORR: July 31, 2010
- Design verification testing including jaw gap and force, cut length, hyperextension, resistance and renal burst pressure

Clinical Studies

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

Conclusions

The results of testing demonstrate the device is as safe, effective, and performs as well as the LigaSure™ Curved, Small Jaw, Open Sealer/Divider, the legally marketed device identified herein.