



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 15, 2015

Covidien
Ms. Nancy Sauer
Product Manager, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K150835

Trade/Device Name: LigaSure Advance Monopolar Tip Laparoscopic
Sealer/Divider, Pistol Grip

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: September 18, 2015

Received: September 24, 2015

Dear Ms. Sauer:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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,

Joshua C. Nipper -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)

K150835

Device Name

LigaSure Advance Monopolar Tip Laparoscopic Sealer/Divider, Pistol Grip

Indications for Use (Describe)

The LigaSure Advance Sealer/Divider is a bipolar/monopolar electro-surgical instrument intended for use in minimally invasive surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Advance Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. The instrument 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, 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 – K150835

Date summary prepared: 10/15/15

510(k) Submitter/Holder

Covidien
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Boulder, CO 80301

Contact

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Name of Device

Trade Name: LigaSure™ Advance Monopolar Tip Sealer/Divider, Pistol Grip
Catalog Numbers: LF5544
Common Name: Monopolar and Bipolar Electrosurgical Instrument
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI).

Predicate Device

The subject device is a legally marketed medical device, manufactured by Covidien llc. The LigaSure Advance family of instruments was cleared under 510(k) K063195. The original LigaSure Advance Monopolar tip devices (LF5034 and LF5044) are the predicate devices for the purpose of this 510(k).

Device Description

The LigaSure™ Advance Monopolar Tip Sealer/Divider, Pistol Grip is a sterile, single-use, hand-held bipolar electrosurgical instrument designed for use with compatible Covidien generators to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during minimally invasive general surgical procedures. The device uses radio frequency (RF) energy to seal vessels, tissue bundles, and lymphatics. A hand actuated mechanism allows the user to open and close the instrument jaws. When the instrument jaws are correctly placed over tissue or vessel to be sealed, the user operates a second control to activate bipolar energy, which seals the tissue. When the sealing cycle is complete, the user operates a separate control to activate a blade, which divides the tissue along the seal line.

The LigaSure Advance Sealer/Divider also includes a tip that can deliver monopolar energy for energy-based dissection and creation of gastrotomies and enterotomies (openings in the stomach or bowel).

Indications for Use

The LigaSure Advance Sealer/Divider is a 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 Advance Sealer/Divider can be used on vessels (arteries and

veins) up to and including 7 mm. The instrument 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, 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.

Technological Characteristics

The LigaSure™ Sealer/Divider works in conjunction with Covidien electrosurgical generators. It is a sterile, single-use device that uses bipolar radiofrequency energy to seal tissues, blood vessels, and lymphatics. The device also uses mechanical action to divide tissue along the seal line.

The LigaSure Advance instrument also provides monopolar electrosurgical output to enable surgeons to dissect through tissue and to create openings (otomies) in the stomach or bowel.

The maximum power output in monopolar mode is 40 watts. The power output in LigaSure mode is controlled by the generator algorithm. The controls for activating LigaSure mode or monopolar energy are present on the instrument handset. The user selects the monopolar power level using controls on the generator.

Comparison to the Predicate Device

The current LigaSure Advance device is very similar to the originally cleared LigaSure Advance. The indications for use have been modified slightly to remove the reference to the compatible generator and to reword the statement for improved clarity. However, there is no change in the tissue types, vessel sizes, or types of procedures where the LigaSure device is indicated.

The ergonomics of the handset have been modified to simplify the controls and to change from an in-line grip to a pistol grip. Technical specifications of the device have not changed.

Performance

Supporting data were obtained from both bench and preclinical testing. Bench testing to support substantial equivalence include:

- Testing in accordance with IEC 60601-1
- Testing in accordance with IEC 60601-2-2
- Testing to show that patient contact materials meet the requirements of the biocompatibility standard, ISO 10993-1
- Testing to support adoption of this device into a validated ethylene oxide sterilization cycle
- Renal artery burst pressure

Preclinical testing for this device includes:

- Sealing and dividing vessels and tissue bundles up to and including 7 mm
- Ability to achieve hemostasis of tissue and vessels
- Thermal spread measurements

Comparative test results showed that the current design performs very similarly to the original design.

Conclusion

The comparison of indications for use, technological characteristics, and performance data show that the current design of the LigaSure Advance device is substantially equivalent to the original design cleared under K03195.