COVIDIEN

510(k) Summary

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Date summary prepared: 8/29/2012

SEP 5 2012

510(k) Submitter/Holder

Covidien llc
5920 Longbow Drive
Boulder, CO 80301

Contact

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Name of Device

Trade Name:	LigaSure™ Curved, Small Jaw, Open Sealer / Divider
Catalog Number:	LF1212
Common Name:	Bipolar electrosurgical instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI).

Purpose of Submission

The purpose of this submission is to modify the indications for use statement to include the specific indication to use the device in ENT procedures and to remove the warning statement surrounding specific surgical procedures around which precision is required. There were no physical changes made to the device associated with the proposed expanded indication; the device design is unchanged from that cleared under K102470.

This submission followed the "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, 2005," the "Guidance for Industry on General / Specific Intended Use,1998," and the "Draft Guidance for Industry and FDA Staff: Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review, 2011."

Predicate Devices

The LigaSure™ Curved, Small Jaw, Open Sealer/Divider was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	LigaSure™ Curved, Small Jaw, Open Sealer/Divider
Device Common Name:	Bipolar electrosurgical instrument
Catalog Number:	LF1212
510(k) Number:	K102470 (cleared 2/7/2011)
Manufacturer:	Covidien, formerly Valleylab, a division of Tyco Healthcare
Trade Name:	LigaSure™ Precise Instrument Vessel Sealing System
Device Common Name:	Bipolar electrosurgical instrument
Catalog Number:	LS1200
510(k) Number:	K010010 (cleared 4/2/2001)
Manufacturer:	Covidien, formerly Valleylab, a division of Tyco Healthcare

Device Description

The LigaSure™ Curved, Small Jaw, Open Sealer/Divider is a sterile, single-use, hand-held bipolar electrosurgical instrument designed exclusively for use with the ForceTriad™ energy platform (generator) to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics during open general surgical

procedures (as indicated). The ForceTriad's tissue-fusion (LigaSure) mode delivers precise energy to tissue for a controlled time period to achieve complete and permanent tissue fusion, and has been designed to produce minimal sticking, charring, or thermal spread to adjacent tissue.

LigaSure instruments attach to the generator with a ten-foot cord containing a "smart" connector. This connector functions as a unique product identifier for device-specific recognition by the generator. The Curved, Small Jaw, Open Sealer/Divider instrument is designed to be both ergonomic and intuitive for the user. Its hemostat-style body and symmetrically placed controls facilitate handling by both left and right-handed users, and its small, curved jaws maximize visibility and access when the instrument is used in confined surgical spaces.

Ring handles function to allow the user to grasp tissue by opening and closing the jaws of the instrument. The interior surfaces of the jaws contain the electrodes, which serve to ligate by delivering energy to the grasped tissue. RF energy can be activated by the user in two ways: (1) through the use of a single button incorporated into the handle body or (2) through the use of a footswitch attached to the generator. A cutting mechanism functions to mechanically divide tissue following tissue fusion. It consists of a stainless steel blade and is controlled by the user through a trigger located on the handle body.

Intended Use

The LigaSure™ Curved, Small Jaw, Open Sealer/Divider is a bipolar electrosurgical instrument intended to be used with the ForceTriad™ energy platform. The instrument is indicated for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive; and including such procedures as bowel resections, gall bladder procedures, Nissen fundoplication, adhesiolysis, etc.

The device 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.

Technological and Performance Characteristics

The LigaSure Curved, Small Jaw, Open Sealer / Divider is the same device as the predicate K102470. The function of the device has not changed. The LigaSure Curved, Small Jaw, Open Sealer/Divider is similar in design and utilizes radio frequency (RF) technology to achieve its intended use similarly to the predicate devices.

Performance Data

The design of the LigaSure Curved, Small Jaw, Open Sealer/Divider is unchanged and the information provided in K102470 is applicable to the device subject of this submission.

Preclinical Bench Testing: Preclinical comparative bench testing for burst pressure and thermal profile was conducted with the LigaSure Curved, Small Jaw, Open Sealer/Divider and its predicates to demonstrate equivalent performance. The subject device was shown to yield higher mean burst pressures on isolated vessels than the predicates; in addition, thermal profile studies showed the subject device has consistently lower mean temperatures than the predicates after single and multiple activations.

Animal Testing: The mean thermal spread of the subject device was shown to be comparable to the predicates for all vessel sizes evaluated.

Usability / Human Factors

Usability was evaluated with users in simulated operating environments, including in the ENT space. These studies consisted of several formative and one summative study, which demonstrate the instrument provides adequate assurance of safety and performance (in regards to human factors/usability aspects) for the patient and operator.

Clinical Literature

An assessment of published clinical literature demonstrates that there is a considerable body of knowledge and experience that shows the use of LigaSure instruments in ENT procedures is safe and effective.

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Substantial Equivalence

In establishing substantial equivalence of the LigaSure Curved, Small Jaw, Open Sealer / Divider to the predicate devices, Covidien EbD evaluated the intended use, indications for use, technological characteristics, reported adverse events, published clinical literature, and instrument risk profiles. The use of the LigaSure Curved, Small Jaw, Open Sealer / Divider in ENT procedures does not raise any new types of questions of safety and effectiveness compared with the predicate devices currently used for these procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Covidien
% Mr. John Van Hoven
Surgical Solutions
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Boulder, CO 80301

SEP 0 5 2012

Re: K113572
Trade/Device Name: LigaSure™ Curved, Small Jaw, Open Sealer / Divider (LF1212)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 29, 2012
Received: August 30, 2012

Dear Mr. Van Hoven:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113572

Device Name: LigaSure™ Curved, Small Jaw, Open Sealer / Divider (LF1212)

Indications for Use:

The LigaSure™ Curved, Small Jaw, Open Sealer / Divider is a bipolar electrosurgical instrument intended to be used with the ForceTriad™ energy platform. The instrument is indicated for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive; and including such procedures as bowel resections, gall bladder procedures, Nissen fundoplication, adhesiolysis, etc.

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Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

E. M. Keith

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113572