K102470

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COVIDIEN

510(k) Summary

Date summary prepared: 2/4/2011

510(k) Submitter/Holder
Covidien, formerly Valleylab, a division of Tyco Healthcare
5920 Longbow Drive
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Contact
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Name of Device
Trade Name: LigaSure™ Curved, Small Jaw, Open Sealer/Divider
Common Name: Bipolar electrosurgical instrument
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI).

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:

Device Common Name: Bipolar electrosurgical instrument
Trade Name: LigaSure™ Precise Instrument Vessel Sealing System
Catalog Number: LS1200
510(k) Number: K010010 (cleared 4/2/2001)
Manufacturer: Covidien, formerly Valleylab, a division of Tyco Healthcare

Device Common Name: Bipolar electrosurgical instrument
Trade Name: LigaSure™ 5mm Laparoscopic Sealer-Divider
Catalog Number: LS1520
510(k) Number: K031011 (cleared 5/29/2003)
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 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

A detailed comparison of the LigaSure Curved, Small Jaw, Open Sealer/Divider LigaSure LS1200 and LS1520 predicate instruments found several technological and performance similarities and very few relevant differences. The following six similarities were identified and discussed in the submission: (1) basic RF tissue fusion technology and its fundamental variables, (2) basic user (manual) control mechanisms, (3) system compatibility, (4) functional materials, (5) dimensions, shape, and weight, and (6) non-clinical and preclinical performance characteristics.

Three differences were found to be relevant when comparing the LigaSure LF1212 instrument to the predicate devices. These differences, identified below, were found to not pose additional or different risks when compared to the instruments already in commercial distribution.

(1) Energy activation mechanisms: The hand-activated button of the LigaSure LF1212 instrument is a single two-stage button design activated through the use of the hemostat-style handles, whereas the hand activation button of the LS1520 instrument is a single-stage design actuated independent of the handle body. The placement of the hand-activated button in this location reduces the number of finger-operated controls. In addition, the ForceTriad's LigaSure touchscreen displays a "hand-activation-on" button (icon). The use of the hand-activated button can be disabled by the user by touching this icon when he/she desires to only activate energy using a footswitch.

(2) Latching/Ratcheting mechanism: Unlike the predicate devices, the LigaSure LF1212 instrument is not designed with a latching/ratcheting mechanism. The non-latching design of the LF1212 instrument is influenced by the placement of the hand-activated button. The location of the hand-activated button requires the instrument handles to be completely closed in order to activate energy, thereby not requiring a latching mechanism in order to assure adequate jaw pressure during activation.

(3) Jaw force/pressure: The jaw pressure of the LF1212 instrument was shown to be lower than the jaw pressure of the LS1200. This lower pressure is due primarily to the 35 percent larger jaw electrode surface area when compared to the LS1200 instrument. A larger electrode surface area is necessary for the instrument to be able to divide the sealed tissue while achieving adequate tissue fusion performance. Notably, the jaw pressure of the LS1520 instrument was found to be comparable to the jaw pressure of the LF1212 instrument.

Non-Clinical/Preclinical Performance

Evidence of safety and effectiveness was obtained from three primary areas: (1) non-clinical (electrical/mechanical/functional) performance testing, (2) preclinical (bench tissue/animal) evaluations and testing, and (3) usability studies.

Non-clinical: Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-2-2, and 60601-1-2. In addition, verification and comparison studies were conducted to evaluate the mechanical and functional performance. Specifically, test results in the following areas were provided: mechanical/functional, cutting mechanism/blade retraction, jaw temperature, jaw force, button force, cutter trigger force, and power curve performance.

Preclinical: Evidence obtained from preclinical bench tissue (in vitro) and animal (in vivo acute and chronic) studies using porcine and ovine models (and in a variety of tissue types and conditions) demonstrate that the LigaSure Curved, Small Jaw, Open Sealer/Divider performs substantially equivalent to the predicate devices in relevant aspects associated with grasping, ligating, and dividing tissue; namely,

Evaluated in vitro using excised porcine renal and pulmonary arteries
-isolated vessel burst pressures/hemostasis
-ligation (sealing) speed
-division (cutting) performance

Evaluated in vivo/acute using porcine and ovine models[1]
-overall hemostasis (isolated arteries, veins, tissue bundles)
-overall activation time
-overall grasping performance
-lateral thermal damage to adjacent tissue (measured on sealed isolated vessels)

Evaluated in vivo/chronic using a porcine model[1]
-overall chronic hemostasis and healing during acute procedures and following a 21-day survival period (isolated arteries, veins, tissue bundles)

[1]evaluation in vivo was necessary because the characteristics requiring evaluation could not be adequately studied in vitro.

Usability: In addition to non-clinical and preclinical testing, usability was evaluated with users in simulated operating environments. 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 Performance

This premarket notification report does not rely on the assessment of human clinical trial data to demonstrate substantial equivalence.

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. David Horton
5920 Longbow Drive
Boulder, CO 80301

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Re: K102470
Trade/Device Name: LigaSure Curved, Small Jaw, Open Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 28, 2011
Received: January 31, 2011

Dear Mr. Horton:

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,

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): K102470

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

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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)

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

510(k) Number K102470