K092879

510(k) Summary or 510(k) Statement

510(k) Summary

OCT 16 2009

1. Submitter Information:

Valleylab, a Division of Tyco Healthcare Group LP
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Boulder, CO
Contact: Philip E. Ake
Senior Regulatory Associate
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2. Name of Device

Trade name: LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider
Common: Bipolar Laparoscopic Electrosurgical Instrument
Classification name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

3. Predicate Devices

The LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider is substantially equivalent to the LigaSure 5mm Laparoscopic Sealer and Divider submitter under K031011. The substantial equivalence letter was dated 5/29/03. This Special 510(k) releases a blunt tip version of 5mm Laparoscopic sealer divider. The primary difference between the LigaSure 5mm Blunt tip Laparoscopic Sealer-Divider and the predicate LigaSure 5mm is the jaw. The jaw of the Blunt Tip version is shaped in a more oval fashion, has a textured surface to improve tissue grasping, and has a longer cut length than the original.

4. Device Description

The LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider is a multi-functional electrosurgical instrument for use with the ForceTriad™ generator when performing laparoscopic surgery. The instrument is capable of sealing vessels and lymphatics, dividing tissue (including vessels) clamped between the jaws, grasping tissue, and blunt dissection. The outer diameter of the instrument shaft is 5mm, with a working length of 37 cm. The following controls are located on the instrument handle

- A lever for opening and closing the instrument jaws. The mechanism incorporates a latch to hold the jaws in the closed position during vessel sealing and cutting
- An activation button for generator power to initiate vessel sealing
- A trigger for actuating the cutter. The cutter can only be actuated when the jaws are closed and latched.
- A knob to rotate the instrument jaws. The jaws can rotate 179 degrees to facilitate surgeon access and visibility.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button, or utilizing a footswitch connected to the generator.

The instrument attaches to the ForceTriad generator via a ten foot cord with a "Smart" connector that identifies the instrument type to the generator. The instrument is supplied sterile for single use.

5. Intended Use

The LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider is a bipolar electrosurgical accessory. It is intended for use with the ForceTriad™ Electrosurgical Generator in general and gynecological, laparoscopic, surgical procedures where the ligations of vasculature (vessels and lymph) is desired.

The device creates a seal by the application of RF electrosurgical energy to vascular structures interposed between the jaws of the instrument. The sealed vessels and other tissue structures may be divided by the deployment of a mechanical knife that resides within the shaft of the instrument and extends forward in a slot within the jaws.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorecotmy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5mm Blunt tip Laparoscopic Sealer-Divider can be used on vessels and lymphatics up to and including 7mm and tissue bundles as large as will fit in the jaws of the instrument.

The LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider can be used to seal Pulmonary Vasculature when used with the ForceTriad™ Electrosurgical generator.

6. Summary of Technology Characteristics

This is a Special 510(k). The changes associated with this 510(k) are primarily related to the device jaw and increased force delivery. This modified 5mm Blunt Tip Laparoscopic Sealer-Divider has the same basic technological characteristics as the predicate LigaSure device. The device will seal vessels and lymph using bipolar RF energy and can mechanically divide the sealed areas or tissue with a mechanical cutting device incorporated into the shaft and jaws. The device can only operate with the ForceTriad Generator.

7. Summary Non-clinical testing

The Non-clinical testing consisted of ex-vivo tissue studies, in-vivo tissue studies (porcine and canine model), and performance verification. The purpose of the testing was to ensure that the device functions as intended, and meets design specifications. This also included testing to the relevant safety standards. The data obtained showed that the device is substantially equivalent to the predicate and meets the safety and effectiveness criteria.

8. Summary of Clinical testing

No clinical testing was conducted. Clinical testing was not necessary to establish substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Valleylab, a Division of Tyco Healthcare Group LP
% Mr. Philip E. Ake, Senior Regulatory Associate
5920 Longbow Drive
Boulder, CO 80301

OCT 16 2009

Re: K092879
Trade/Device Name: LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 17, 2009
Received: September 18, 2009

Dear Mr. Ake:

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.

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 (240) 276-3150 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): _____

Device Name: LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider

Indications for Use:

The LigaSure 5mm, Blunt tip, Laparoscopic Sealer- Divider is a bipolar electrosurgical instrument intended for use the ForceTriad Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorecotmy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5mm Blunt tip Laparoscopic Sealer-Divider can be used on vessels and lymphatics up to and including 7mm and tissue bundles as large as will fit in the jaws of the instrument.

Prescription Use ___X___ (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)

FOR M-MELKERSON

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

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