SEP 2 8 2004

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Valleylab LigaSure™ Open Dissector Divider

K041587

1. Submitter Information

Valleylab
A division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Charles M. Copperberg
Manager, Regulatory
Telephone: 303-530-6247

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Date summary prepared: September 20, 2004

2. Name of Device

Trade or Proprietary Name: LigaSure™ Open Dissector Divider, Catalog Number LS4100

Common Name: Bipolar, Open Electrosurgical Instrument

Classification Name:

- Electrosurgical Cutting and Coagulation Device and Accessories, and
- Gynecologic Electrocautery and Accessories

3. Predicate Devices

The LigaSure™ Open Dissector Divider (catalog number LS4100) is substantially equivalent to the following legally marketed devices:

- For configuration, sealing and dissection capabilities the LS4100 is substantially equivalent to the Valleylab LS1200 LigaSure™ Precise Instrument (K010010)

- For cutting capabilities, the LS4100 is substantially equivalent to the Valleylab LS1500 LigaSure™ 5mm Laparoscopic Sealer-Divider Instrument (K031011)

4. Device Description

The LigaSure Open Dissector Divider is a multi-functional, electrosurgical instrument intended for use with the LigaSure Vessel Sealing Generator (K981916) when performing open surgery. The instrument is capable of sealing and dividing vessels and tissue clamped between its jaws, grasping tissue, and dissection. Sealing of vessels and tissue containing vessels can be activated

using the activation button on the device or via a footswitch. The instrument also incorporates a mechanical cutting mechanism that divides tissue.

The instrument attaches to the LigaSure™ generator with a ten (10) foot cable and a "smart" connector that identifies the instrument type to the generator. The instrument is supplied sterile for single-use.

5. Intended Use

The LigaSure™ Open Dissector Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in open, general and gynecologic surgical procedures where ligation and division of vessels is desired. This device creates ligation by application of bipolar electrosurgical RF energy and pressure to vessels/tissue interposed between the jaws of the device. The ligation can then be transected using the built in cutting mechanism. The device can be used for vessels up to and including 7 mm in diameter and tissue bundles as large as will fit into the jaws of the instrument.

Indications for use include general, open procedures including urologic, vascular, thoracic, and plastic and reconstructive, procedures where dissection, ligation and division of vessels are performed such as: spleenectomies, thryoidectomies, nephrectomies, prostatectomies, bowel resection and colectomy.

The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

6. Summary of Technological Characteristics

The LigaSure™ Open Dissector Divider has the same basic technological characteristics as the predicate devices noted above.

7. Performance Data

Performance (bench) testing and a preclinical study were done to ensure that the LigaSure™ Open Dissector Divider functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2004

Mr. Charles M. Copperberg
Manager, Regulatory
Valleylab
5920 Longbow Drive
Boulder, Colorado 80301

Re: K041587
Trade/Device Name: LigaSure™ Open Dissector Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 14, 2004
Received: September 15, 2004

Dear Mr. Copperberg:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041587

Device Name: LigaSure™ Open Dissector Divider

Indications for Use:

The LigaSure™ Open Dissector Divider is a bipolar electrosurgical instrument intended for use with the LigaSure™ Generator in open, general, surgical procedures where dissection, ligation and division of vessels is desired. This device creates ligation by application of bipolar electrosurgical RF energy and pressure to vessels/tissue interposed between the jaws of the device. The ligation can then be transected using the built in cutting mechanism. The device can be used for vessels up to and including 7 mm in diameter and tissue bundles as large as will fit into the jaws of the instrument.

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The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041587

(Posted November 13, 2003)