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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

K043273

LigaSure™ Vessel Sealing System

1. Submitter Information

Valleylab
A Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert W. Vinson
Senior Regulatory Associate
Telephone: 303-530-6469
Fax: 303-530-6313
E-mail: Herb.Vinson@Tycohealthcare.com

Date summary prepared: November 24, 2004

2. Name of Device

Trade or Proprietary Name: LigaSure™ Vessel Sealing System

Common/Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

3. Predicate Devices

The LigaSure™ Vessel Sealing System is substantially equivalent to the following legally marketed medical devices:

- LigaSure™ Vessel Sealing System (K981916)

4. Device Description

The LigaSure™ Vessel Sealing System consists of a microprocessor-based radio-frequency (RF) generator and a selection of instruments designed to be used exclusively with the LigaSure™ generator. All of the instruments are capable of sealing vessels up to, and including, 7mm, and tissue bundles as large as can fit in the jaws of each instrument. When a LigaSure™ instrument is applied to a vessel or tissue bundle and RF energy is applied, the collagen and elastin in the tissues are reformed by heat and pressure to fuse vessel walls, thereby forming a permanent seal. The microprocessor in the generator monitors the tissue properties, stops the application of energy, and allows a brief period of cooling before indicating that the seal cycle is complete.

No changes are being made to the design or operation of any of the devices within the current system. The change as proposed in this 510(k) notification is to the intended use as described above and the resulting labeling changes.

5. Intended Use

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments intended for use in general, laparoscopic and gynecologic surgical procedures where ligation of vessels, including lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general (including urologic, thoracic, plastic and reconstructive), laparoscopic, and gynecological procedures where ligation of vessels is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholesystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7mm and bundles as large as will fit in the jaws of the instruments.

6. Summary of Technological Characteristics

The technological characteristics of the LigaSure™ Vessel Sealing System have not been modified.

7. Performance and Clinical Data

Pre-clinical studies have shown that the LigaSure™ Vessel Sealing System effectively seals lymphatic vessels, producing seals with burst pressures substantially greater than the physiologic pressures in the vessels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2005

Mr. Herbert W. Vinson
Senior Regulatory Associate
Valleylab
A Division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, Colorado 80301

Re: K043273
Trade/Device Name: LigaSure™ Vessel Sealing System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 24, 2004
Received: November 26, 2004

Dear Mr. Vinson:

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 (240) 276-0115. 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,

for Miriam C. Provost

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): K043273

Device Name: LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments intended for use in general, laparoscopic and gynecologic surgical procedures where ligation of vessels, including lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

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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 AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (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 K043273