

AUG 28 1998

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
VALLEYLAB LIGASURE™ VESSEL SEALING SYSTEM**

I. Submitter Information

Valleylab Inc
a division of United States Surgical Corporation
5920 Longbow Drive
Boulder, Colorado 80301
Contact: Charles M. Copperberg
Telephone No.: 303-530-6343

K981916

Date Summary Prepared: 08/27/98

II. Name of Device

Proprietary Name: LigaSure™ Vessel Sealing System including the LigaSure™ Vessel Sealing Generator and LigaSure™ Open and Laparoscopic Instruments

Common or Usual Name: Bipolar Electrosurgical Generator with bipolar electrosurgical open and laparoscopic instruments

Classification Name: CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories and 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

III. Predicate Devices

The LigaSure™ Vessel Sealing Generator is a bipolar generator which is substantially equivalent to the following Valleylab electrosurgical generators: Force FX (K944602), Force 300 (K953195) and NS2000 (K946177).

The LigaSure™ Open and Laparoscopic Instruments are substantially equivalent to the Cabot Seitzinger Tripolar Forceps, the Cabot Bipolar Cutting Forceps (K932293 and K946109) and the Storz Bipolar Forceps (K960009). All of these devices perform the coagulation of tissue via bipolar RF energy applied through the electrodes of the devices.

IV. Device Description

The LigaSure™ Vessel Sealing Generator is an isolated, microprocessor based, bipolar only electrosurgical generator which incorporates three bipolar modes; standard, macro and vessel sealing. The generator will accept standard bipolar devices. In addition, the generator will also accept dedicated LigaSure™ Open and Laparoscopic Instruments for use in vessel sealing.

The LigaSure™ Open instruments are reusable forceps type devices with "snap-in" single use, disposable electrodes which are placed in the jaws of the devices. The LigaSure™ laparoscopic

instrument is a sterile, single use device for use in grasping and vessel sealing in laparoscopic procedures. The device outer diameter is 5 mm and the working length is approximately 32 cms.

The system creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

V. Intended Use

The LigaSure™ Vessel Sealing System is intended for use in general, laparoscopic, and gynecologic procedures where ligation of vessels is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

Indications for use for this type of ligation include general, laparoscopic and gynecological procedures such as urological, thoracic, plastic and reconstructive, bowel resections, hysterectomies (LAVH and abdominal) cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

VI. Summary of Technological Characteristics

The LigaSure™ Vessel Sealing generator and instruments have the same basic technological characteristics as the predicate devices noted above. The LigaSure™ generator provides bipolar RF energy to bipolar devices for coagulation/desiccation of vessels.

VII. Performance Data

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the devices functioned as intended and met design specification. Sufficient data was obtained to show the LigaSure™ Vessel Sealing system was equivalent to or better than the predicate devices and meet safety and effectiveness criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 28 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Charles Copperberg
Senior Regulatory Affairs Associate
ValleyLab, Inc.
5920 Longbow Drive
Boulder, Colorado 80301

Re: K981916
Trade Name: Ligasure Vessel Sealing System
Regulatory Class: II
Product Code: GEI
Dated: May 29, 1998
Received: June 1, 1998

Dear Mr. Cooperberg:

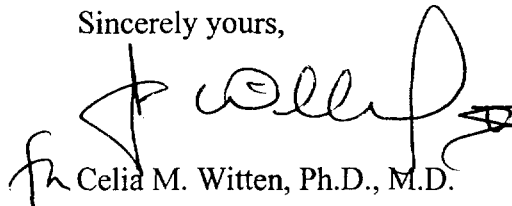
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

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510(k) Number (if known): K981916Device Name: Valleylab 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 procedures where ligation of 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 cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 2.1 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

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