USER: MCINTOSH-LITTLE, KIMBERLY B (kml)

FOLDER: K031011 - 62 pages (FOI:08530400)

COMPANY: VALLEYLAB, INC. (VALLEYLAB)

PRODUCT: ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES (GEI)

SUMMARY: Product: LIGASURE 5MM LAPAROSCOPIC SEALER-DIVIDER, MODEL LS1500

DATE REQUESTED: Thu Jul 01 24:00:00 2010

DATE PRINTED: Wed Oct 27 06:28:05 2010

Note: Releasable Version

Table of Contents

MAY 2 9 2003

K031011

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider

1. Submitter Information

Valleylab, Inc.
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert Vinson
Telephone: 303-530-6469

Date summary prepared: March 11, 2003

2. Name of Device

Trade or Proprietary Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Common Name: Bipolar Laparoscopic Electrosurgical Instrument

Classification Name:
- Electrosurgical Cutting and Coagulation Device and Accessories, and
- Gynecologic Electrocautery and Accessories

3. Predicate Devices

The Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider is substantially equivalent to the Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916), and the Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013). All three of these devices are used in laparoscopic surgery to seal vessels by the application of RF energy to the vessels and tissues interposed between the jaws of the instrument. The LigaSure™ 5mm Laparoscopic Sealer-Divider and the LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument divide tissue using a surgeon-actuated blade.

4. Device Description

The LigaSure 5mm Laparoscopic Sealer-Divider is a multi-functional electrosurgical instrument for use with the LigaSure Vessel Sealing Generator (K981916) when performing laparoscopic surgery. The instrument is capable of sealing vessels, dividing vessels and tissue clamped between its jaws, grasping tissue, and blunt dissection. The outer diameter of the instrument shaft is 5mm,

with a working length of 37 cm. Controls are located on the instrument handle. All controls can be operated with either the right or left hand.

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

5. Intended Use

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

Indications for use include general laparoscopic surgical procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure 5mm Vessel Sealer-Divider 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 Vessel Sealer-Divider can be used on vessels up to and including 7mm diameter, and tissue bundles as large as will fit in the jaws of the instrument.

6. Summary of Technological Characteristics

The LigaSure™ 5mm Laparoscopic Sealer-Divider has the same basic technological characteristics as the predicate devices noted above.

7. Performance Data

Performance testing and pre-clinical studies were performed to ensure that the LigaSure™ 5mm Laparoscopic Sealer-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

MAY 2 9 2003

Mr. Herbert Vinson
Senior Regulatory Associate
Valleylab, Inc.
5920 Longbow Drive
Boulder, Colorado 80301

Re: K031011
Trade/Device Name: LigaSure™ 5mm 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: March 11, 2003
Received: March 31, 2003

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K031011

Device Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Indications For Use:

The LigaSure™ 5mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels) 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 laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. 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.

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

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 K031011

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2003

Mr. Herbert Vinson
Senior Regulatory Associate
Valleylab, Inc.
5920 Longbow Drive
Boulder, Colorado 80301

Re: K031011
Trade/Device Name: LigaSure™ 5mm 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: March 11, 2003
Received: March 31, 2003

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.

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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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

2

510(k) Number (if known): K031011

Device Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Indications For Use:

The LigaSure™ 5mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels) 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 laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. 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.

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

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 K031011

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

3

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 31, 2003

VALLEYLAB, INC.
5920 LONGBOW DRIVE
BOULDER, CO 80301
ATTN: HERBERT VINSON

510(k) Number: K031011
Received: 31-MAR-2003
Product: LIGASURE 5MM LAPAROSCOPIC SEALER-DIVIDER, MODEL LS1500

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

12

K031011

March 11, 2003

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

FDA/CDRH/ODE/DMC
2003 MAR 31 P 3:24

Re: Section 510(k) Notification

Attention: Documentation Clerk

Valleylab is submitting two (2) copies of the information required for notification under Section 510(k) of the Food, Drug and Cosmetic Act, as amended, for distribution of the LigaSure™ 5mm Laparoscopic Sealer-Divider.

Valleylab considers our intent to market this device for the indications described herein to be confidential information, and therefore, exempt from public disclosure. Portions of this submission may be considered to be trade secrets and/or confidential information. These sections, if any, have been marked as confidential and should be treated as such even after marketing commences.

All correspondence related to this submission should be addressed to the attention of the undersigned.

Sincerely,

VALLEYLAB

Herbert Vinson

Herbert Vinson
Senior Regulatory Associate

Attachments

SU II

SK 47

13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: **002139-956733**

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufmaThe following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the premarket application.) Also remember that the Payment Identification Number must be written on the check.
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

VALLEYLAB, INC.
5920 LONGBOW DRIVE
BOULDER, CO 80301-3299
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
020502162

2. CONTACT NAME
HERBERT VINSON

2.1 E-MAIL ADDRESS
herb.vinson@tycohealthcare.com

2.2 TELEPHONE NUMBER (Include Area Code)
303-530-6469

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
303-530-6313

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party
- ☐ Biologic License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA, PMR)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF THE USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS APPLICATION

$2,187.00

14

CDRH SUBMISSION COVER SHEET

Date of Submission: 3-11-03 **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☒ *Notice of intent to start clinical trials* ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: X Traditional ☐ *Special* ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B ***Applicant or Sponsor***

Company/Institution Name: Valleylab, Inc.		Establishment registration number: 1717344	
Division Name (if applicable):		Phone number (include area code): 303-530-6469	
Street Address: 5920 Longbow Drive		Fax number (include area code): 303-530-6313	
City: Boulder	State/Province: Colorado	Zip code: 80301	Country: USA

Contact Name: Herbert Vinson

Contact Title: Senior Regulatory Associate	Contact e-mail address: herb.vinson@tycohealthcare.com

Section C **Submission Correspondent (if different from above)**

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country

Contact Name:

15

Section D1 — Reason for Submission – PMA,PDP, or HDE

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

X New Device
☐ Additional or expanded indications
☐ Other reason (specify):

☐ Change in technology
☐ Change in design

☐ Change in materials
☐ Change in manufacturing process

Section E **Additional Information on 510(k) Submissions**

1. uct codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data:
1 79GEI	2 85HGI	3	4	X 510(k) summary attached
5	6	7	8	☐ 510(k) statement

510(k) Number	Trade of Proprietary or model name	Manufacturer
K981916	1 LS1000 LigaSure™ LAP Laparoscopic Instrument	1 Valleylab, Inc.
K010013	2 LS1100 LigaSure ATLAS™ Laparoscopic Instrument	2 Valleylab, Inc.
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name: Bipolar Laparoscopic Electrosurgical Instrument

Trade or proprietary or model name	Model Number
1 LigaSure™ 5mm Laparoscopic Sealer-Divider	1 LS1500
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: X Laboratory Testing X Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: 79 GEI 85 HGI	C.F.R. Section 21CFR 878.4400 21CFR 878.4120	Device Class: ☐ Class I X Class II ☐ Class III ☐ Unclassified
Classification Panel: 79 – General and Plastic Surgery Devices, 85 – Obstetrics and Gynecology		
Indications (from labeling): Vessel sealing during general and gynecologic laparoscopic electrosurgery		

17

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

X Original ☐ Add ☐ Delete	FDA establishment registration number: 1717344	X Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name: Valleylab, Inc.		Establishment registration number: 1717344	
Division name (if applicable):		Phone number (include area code): 303-530-6469	
Street address: 5920 Longbow Drive		FAX number (include area code): 303-530-6313	
City Boulder	State/Province CO	Zip code: 803031	Country USA
Contact name: Herbert Vinson			
Contact title: Senior Regulatory Associate			

Original ☐ Add ☐ Delete	FDA Establishment registration number: (b) (4)	☐ Manufacturer ☐ Contract Manufacturer	X Contract Sterilizer ☐ Repackager/relabeler
Company/Institution Name: (b) (4)		Establishment registration number: (b) (4)	
Division name (if applicable):		Phone number (include area code): (b) (4)	
Street address: (b) (4)		FAX number (include area code): (b) (4)	
City: (b) (4)	State/Province: (b) (4)	Zip code: (b) (4)	Country: (b) (4)
Contact name: (b)			
Contact title: (b) (4)		Contact e-mail address: (b) (4)	

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:		Contact e-mail address:	

Section 510(k) Notification

LigaSure™ 5mm Laparoscopic Sealer-Divider

March 11, 2003

Valleylab, Inc.
5920 Longbow Drive
Boulder, Colorado 80301

Table of Contents
LigaSure™ 5mm Laparoscopic Sealer-Divider.

SECTION 510(K) NOTIFICATION

Valleylab, Inc.
5920 Longbow Drive
Boulder, CO 80301

A. Name of Device

Trade or Proprietary Name: LigaSure™ 5mm Laparoscopic Sealer-Divider
(Catalog Number LS1500)

Common Name: Bipolar Laparoscopic Electrosurgical Instrument

Classification Name:

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

B. Establishment Registration

Valleylab, Inc.
5920 Longbow Drive
Boulder, CO 80301
Registration Number 1717344

The LigaSure™ 5mm Laparoscopic Sealer-Divider will be sterilized by :

(b) (4) [redacted]

C. Classification

Regulatory Class: Class II
Product Code: 79GEI and 85HGI
Classification Panel: Panel 79 – General and Plastic Surgery Devices
Panel 85 – Obstetrics and Gynecology
Regulation Numbers: 21CFR 878.4400, and 21CFR 884.4120.

D. Conformance with Section 514 Performance Standards

Performance standards have not yet been promulgated for this device classification, therefore, Section 514, Performance Standards, of the Food Drug and Cosmetic Act, as amended, does not apply.

E. Product Labeling

Labeling for the LigaSure™ 5mm Laparoscopic Sealer-Divider includes product identification, cautions and warnings to the operator, contraindications, and instructions for use. Draft product labeling is provided in Attachment 3.

Product labeling for the LigaSure Vessel Sealing Generator (K981916) will be modified to add the LigaSure™ 5mm Laparoscopic Sealer-Divider (catalog number LS1500) to the accessories list. The LigaSure Vessel Sealing Generator operating instructions require no changes.

F. Advertising

Advertising has not been prepared at this time.

G. Intended Use

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

Indications for use include general laparoscopic surgical procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure 5mm Vessel Sealer-Divider 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 Vessel Sealer-Divider can be used on vessels up to and including 7mm diameter, and tissue bundles as large as will fit in the jaws of the instrument.

A separate statement of the indications for use is provided in Attachment 2.

H. Product Description

The LigaSure 5mm Laparoscopic Sealer-Divider is a multi-functional electrosurgical instrument for use with the LigaSure Vessel Sealing Generator (K981916) when performing laparoscopic surgery. The instrument is capable of sealing vessels, dividing vessels and tissue clamped between its 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 handle/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 with the LigaSure generator footswitch.

The instrument attaches to the LigaSure generator with a "smart" connector that identifies the instrument type to the generator, and a ten (10) foot cord. The instrument is supplied sterile for single use. Refer to Attachment 4 for an illustration of the instrument.

I. Device Components

The main components of the LigaSure™ 5mm Laparoscopic Sealer-Divider are shown in Table 1.

Table 1

Component	**Major Function**
Handle (moveable)	Opens and closes the jaws. Locks the jaws to apply pressure for vessel sealing.
Jaws	Open and close to manipulate and grasp tissue. Clamp vessels/tissue for sealing and cutting. The jaws are the electrodes for applying vessel-sealing RF energy.
Shaft	5mm diameter and 37cm length for laparoscopic access.
Rotation Wheel	Allows the surgeon to rotate the jaws to the desired position.
Cutting Trigger	Actuates the cutting mechanism.
Activation Button	Activates the RF energy for vessel sealing.
Cord with Smart Connector	Connects the instrument to the LigaSure generator, and informs the generator which type of instrument is connected.

J. Packaging Materials

The LigaSure™ 5mm Laparoscopic Sealer-Divider will be packaged in a single unit PETG tray with a Tyvek lid that is designed to allow penetration of ethylene oxide gas during sterilization. Packaging materials are identical to those used for other Valleylab sterile, single-use accessories.

K. Method of Sterilization

The LigaSure™ 5mm Laparoscopic Sealer-Divider will be sterilized by (b) (4) ethylene oxide (EtO) sterilization, which will be performed in accordance with validated and periodically audited sterilization procedures using the "overkill" method, according to ISO 11135:1994(E), "Medical Devices–Validation and Routine Control of Ethylene Oxide Sterilization." The sterility assurance level (SAL) for the product will be 10^{-6}. Sterility testing will be conducted on each sterilization run using B. subtillis var. niger spore strips.

EtO decay curves will be determined to ensure that residuals are at safe levels prior to product release. Product will have appropriate release limits for EtO and associated residuals as listed in AAMI/ANSI/ISO 10993-7, "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residents."

Bioburden monitoring of the manufacturing area and of the finished product will be performed on an ongoing basis.

L. Safety and Performance

L.1 Biocompatibility Testing:

The biological safety of the LigaSure™ 5mm Laparoscopic Sealer-Divider has been assured through the selection of materials that demonstrate appropriate levels of biocompatibility. All patient contacting materials have been, or are being tested in accordance with "BS EN 30993-1:1994/ISO 10993-1:1992, Biological Evaluation of Medical Devices, Part 1," and must pass these requirements prior to release of the product. The LigaSure™ 5mm Laparoscopic Sealer-Divider is categorized, per ISO 10993-1 section 5.1.3 and 5.2, as "Externally Communicating Devices, Blood Path Indirect, Contact Duration Category A."

See Attachment 5 for the listing of biocompatibility testing performed on patient contact components.

L.2 Electrical Testing:

The LigaSure™ 5mm Laparoscopic Sealer-Divider has been designed to conform to the applicable sections of the following standards.

- IEC 60601-1 (1995), Medical Electrical Equipment Part 1: General Requirements for Safety

- IEC 60601-1-1 (1992), Medical Electrical Equipment Part 1: General Requirements for Safety, 1. Collateral Standard: Safety Requirements for Medical Electrical Systems

- IEC 60601-2-2 (1998), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment

- ANSI/AAMI HF18 (1993), Electrosurgical Devices

Electrical testing has been completed on pre-production devices, and will be repeated on production devices prior to product release.

L.3 Performance Validation:

Performance testing was completed in the laboratory to evaluate the sealing capabilities of the LS1500 LigaSure™ 5mm Laparoscopic Sealer-Divider. The results were compared with the results of similar testing using the Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916) and the Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013).

Excised porcine renal arteries were used for this study due to their similarity to humans in size and composition. The arteries were categorized into three size ranges: 0 - 2.0mm, 2.1 - 4.0mm, and 4.1 to 7.0mm. Vessels were sealed and divided. Thermal spread and seal burst strength were determined. (Thermal spread is visible as a blanching of tissue adjacent to the seal area. Burst strength is determined by pumping water into each vessel at a constant rate until failure.) The results of burst testing and thermal spread are shown in Table 2 for each vessel size range.

Table 2

LS1500 5mm Laparoscopic Sealer-Divider Seal Performance					
Vessel Size	**Sample Size**	**Average Burst Pressure (mmHg)**	**Burst Pressure Range (mmHg)**	**Probability of Burst Pressure 360mmHg or Greater**	**Average Thermal Spread (mm)**
All Vessels	48	1037	385 – 1700[1]	97%	1.40
Small (0-2mm)	12	1030	385 - 1546	97%	0.94
Medium (2.1-4mm)	19	1024	480 – 1700[1]	98%	1.44
Large (4.1-7mm)	17	1056	455 - 1700[1]	95%	1.82

[1]1700mmHg is the maximum measurable value for the test equipment used.

Burst strength and thermal spread comparison data for LS1500, LS1000 and LS1100 are shown in Table 3.

Table 3

Product Comparison: Burst Strength and Thermal Spread				
Instrument	**Average Thermal Spread (mm)**	**Average Burst Pressure (mmHg)**	**Burst Pressure Range (mmHg)**	**Probability of Burst Pressure 360mmHg or Greater**
LS1500	1.40	1037	385 – 1700[2]	97%
LS1000[1]	<2.0	1035	0 - 3313[2]	>87%
LS1100[1]	<2.0	1050	285 - 1700[2]	>93%

[1]Data taken from 510(k) submissions.

[2]Burst measurement instruments used for LS1100 and LS1500 were limited to a maximum measurement value of 1700mmHg. Instruments used for LS1000 testing had a maximum measurement value exceeding 3313mmHg.

Average burst pressure for the LS1500 5mm Laparoscopic Sealer-Divider is between the average pressure for LS1000 and LS1100. The burst values for all three instruments are essentially identical. Minimum burst pressure for LS1500 is higher than the minimum burst for either LS1000 or LS1100. All seals obtained with LS1500 were greater than 3 times normal systolic pressure (120mmHg). The calculated probability of obtaining a seal with a burst pressure of 360mmHg or greater with the LS1500 is 97%.

Average thermal spread for LS1500 is 1.40mm, less than the average thermal spread of the LS1000 or LS1100 instruments. Thermal spread is the width of tissue adjacent to the edge of the instrument that is damaged by heat as the vessel is sealed.

L.4 Pre-clinical Testing

An acute animal study (canine) was conducted to further evaluate the performance of the LigaSure 5mm Laparoscopic Sealer-Divider, and to compare performance with the LS1000 and LS1100. Forty-eight (48) individual vessels (arteries and veins) and tissue bundles across the size range 1.5 – 7.6mm were sealed using the LS1500. Additionally, 10 seals were made with the LS1000 and 12 with the LS1100. (Refer to Table 4.)

All seals were divided and observed for a minimum of 15 minutes for evidence of bleeding through the seal area. No bleeding occurred through any of the seals with any of the instruments. One vessel sealed with LS1500 and one vessel sealed with LS1000 bled at a minute pinhole in the vessel wall immediately adjacent to the seal. The pinholes were apparently caused by mechanical manipulation of the vessel. In each instance, the bleeding stopped immediately by spontaneous coagulation (no intervention required).

Table 4

Instrument	Number of Seals	Number of Seals Exhibiting Bleeding After Division	Comments
LS1500	48	0	One pinhole in vessel wall adjacent to seal due to mechanical manipulation of the vessel. Immediate spontaneous coagulation without intervention
LS1000	10	0	One pinhole in vessel wall adjacent to seal due to mechanical manipulation of the vessel. Immediate spontaneous coagulation without intervention.
LS1100	12	0	

The cutters in the LS1500 and the LS1100 were used to divide seals. After the seal had been made, and the cutter activated, an assessment was made to determine the length of cut, occurrence of bleeding, and tissue damage. As noted above, there was no bleeding through any seal. Cutting did not damage sealed tissue or adjacent tissue in any instance. Cut length was assessed as a percent of the total travel length of the cutter.

Forty-five (45) cuts were attempted with the LS1500. Thirty-two (32) cuts were 100% length. One (1) additional cut that appeared to be full length could not be measured because the thin tissue was under tension and immediately tore beyond the cut zone. Three (3) additional cuts were 70-80% length because the operator did not fully actuate the cutter trigger. One (1) cut was unsuccessful because the cutter was impeded by tissue debris in the instrument jaws.

All of the LS1500 instruments were prototypes, incorporating materials and assembly methods that were not representative of production devices. Consequently, eight (8) attempted cuts were partially or completely unsuccessful for the following reasons.

- Misassembly of the cutter (2)
- Misadjustment and/or wear of prototype components (6)

Complete actuation of the cutter trigger, and cleaning the instrument jaws, are addressed in the Instructions For Use. (See Attachment 3.) Device malfunction related to prototype instruments will be resolved in production instruments. The function of the LS1500 cutter will be fully validated prior to product release to assure high reliability.

Twelve (12) seals were divided with the LS1100: all at 100 percent cut length.

M. Summary of Safety and Effectiveness

A summary of safety and effectiveness information for the LigaSure™ 5mm Laparoscopic Sealer-Divider can be found in Attachment 7.

N. Statement of Substantial Equivalence

The LigaSure™ 5mm Laparoscopic Sealer-Divider (catalog number LS1500) is substantially equivalent in function and intended use to the following legally marketed devices:

- Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916)
- Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013)

The LS1000 is a laparoscopic LigaSure surgical instrument similar to the LigaSure™ 5mm Laparoscopic Sealer-Divider, except that the LS1000 does not have capability to cut tissue. The LS1000 is 5mm in diameter, with a working length of 32 cm. It seals vessels up to, and including, 7mm in diameter.

The LS1100 is a laparoscopic LigaSure surgical instrument similar to the LigaSure™ 5mm Laparoscopic Sealer-Divider. The LS1100 is 10mm in diameter, with a working length of 37 cm. It seals vessels up to, and including, 7mm in diameter. The LS1100 also has a surgeon-actuated cutter to divide tissue interposed in the jaws of the instrument.

Table 5

Comparison of the LigaSure™ 5mm Laparoscopic Sealer-Divider to Predicate Devices			
Characteristic	LigaSure™ 5mm Laparoscopic Sealer-Divider (LS1500)	LigaSure™ LAP Laparoscopic Instrument (LS1000)	LigaSure ATLAS™ Laparoscopic Sealer-Divider (LS1100)
Sterile, single-use	Yes	Yes	Yes
Size of vessels sealed	≤7mm	≤7mm	≤7mm
Mean seal burst pressure	1037 mmHg	1035 mmHg	1050 mmHg
Cuts tissue	Yes	No	Yes
Other functional capabilities	Grasping, blunt dissection	Grasping, blunt dissection	Grasping, blunt dissection
Working length	37cm	32cm	37cm
Working diameter	5mm	5mm	10mm
Instrument rotation	Yes	Yes	Yes

Product literature for the predicate devices, LS1000 and the LS1100, is included in Attachment 6.

O. Further Information

In the event that additional information is required, please contact:

Herbert Vinson
Senior Regulatory Associate
5920 Longbow Drive
P.O. Box 9015
Boulder, CO 80301

Phone: 303-530-6469
Fax: 303-530-6313

List of Attachments

Attachment 1	*Truthful and Accuracy Statement*
Attachment 2	Indications for Use
Attachment 3	Draft Product Labeling: Instructions for Use
Attachment 4	Product Illustration
Attachment 5	Materials Biocompatibility
Attachment 6	Product Literature for Predicate Devices (LS1000 & LS1100)
Attachment 7	Summary of Safety and Effectiveness

Attachment 1

TRUTHFUL and ACCURACY STATEMENT

TRUTHFUL AND ACCURACY STATEMENT

Pursuant to 21 CF 807.87(j), I, Herbert Vinson, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Senior Regulatory Associate of Valleylab, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Herbert Vinson

Signature

Herbert Vinson

Date 3-11-03

32

Attachment 2

INDICATIONS FOR USE

510(k) Number (if known): K031011

Device Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Indications For Use:

The LigaSure™ 5mm Vessel Sealer-Divider is a bipolar electrosurgical instrument intended for use with the LigaSure Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels) 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 laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Attachment 3

DRAFT PRODUCT LABELING

- **INSTRUCTIONS FOR USE**
  LigaSure™ 5mm Laparoscopic Sealer-Divider
  Catalog Number LS1500

- **UNIT PACKAGE LABEL**

- **CASE LABEL**

Valleylab™

LigaSure™ 5mm Sealer/ Divider

for use with the LigaSure Vessel Sealing System

REF **LS1500**

℞ ONLY

Latex Free

Single Use Only

STERILE

DRAFT

36

EN

LigaSure™ 5mm Laparoscopic Sealer/ Divider

for use with the LigaSure vessel sealing system

REF **LS1500** LigaSure 5mm instrument with cutter.

Before surgery, read all instructions and precautions provided with this instrument and LigaSure generator to be used.

Warning

The LS1500 laparoscopic sealer/divider is intended for use ONLY with the Valleylab LigaSure Vessel Sealing System. Use of this instrument with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team, or cause damage to the instrument.

Place the vessel or tissue in the center of the jaws. To avoid incomplete vessel sealing, do not grasp tissue beyond the electrode surface; do not place tissue in the jaw hinge.

Do not use this device on vessels in excess of 7 mm in diameter.

The LigaSure vessel sealing system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Electric Shock Hazard Do not connect wet accessories to the LigaSure generator.

Fire Hazard Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire. When not using instruments, place them in a clean, dry, *highly visible area not in contact with the patient.* Inadvertent contact with the patient may result in burns.

Confirm proper LigaSure generator settings before proceeding with surgery.

For laparoscopic procedures, be alert to these potential hazards:

The external surfaces of the instrument jaws may remain hot enough to cause burns after the RF current is deactivated.

Inadvertent activation or movement of the activated instrument outside of the field of vision may result in injury to the patient.

Do not activate the instrument while instrument jaws are in contact with, or in close proximity to, other instruments including metal cannulas, as localized burns to the patient or physician may occur.

Do not activate the LigaSure generator in an open circuit condition. Activate the generator only when the instrument is in direct contact with the target tissue to lessen the possibility of unintended burns.

Carefully insert and withdraw instruments from cannulas to avoid possible damage to the devices and/or injury to the patient.

Warning

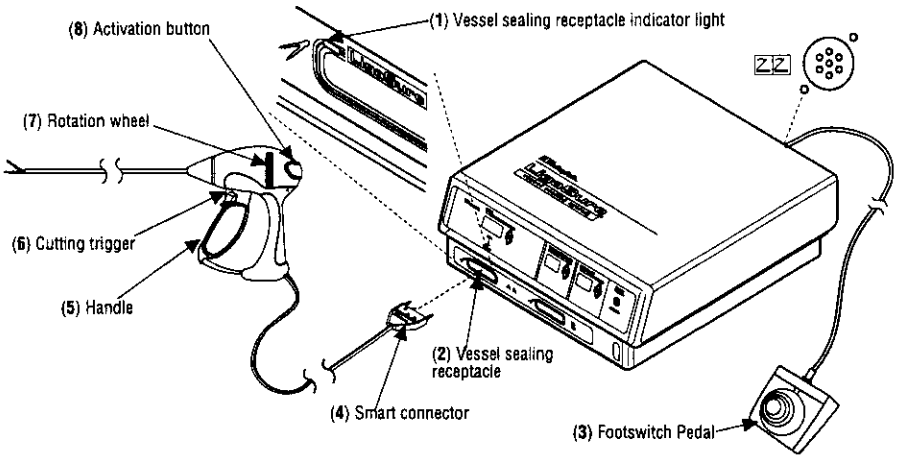
Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to the instrument may carry electrical current or heat, which may cause unintended burns to the patient. Remove fluid from around the instrument jaws before activating the instrument.

Always keep the external surface of the instrument jaws away from adjacent tissue while activating the LigaSure generator.

Inspect the instrument and cords for breaks, cracks, nicks, or other damage before use. If damaged, do not use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team or cause damage to the instrument.

Do not reuse or resterilize this device.

Position instrument cords to avoid contact with the patient or other leads. Do not wrap cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.



Set Up

With the black dots on the connector facing up, firmly insert the Smart Connector (**4**) into the left, purple and blue vessel sealing receptacle (**2**) on the generator front panel. Ensure that the vessel sealing receptacle indicator light (**1**) changes from red to green.

Select the desired intensity setting. The suggested setting is 2 to 3 bars: use 2 for smaller tissue volume, and 3 for larger tissue volume.

During Surgery

Tissue manipulation and dissection:

The instrument can be used to manipulate and dissect tissue with the jaws either open or closed.

To rotate the electrode:

Turn the gray rotation wheel (**7**) on the handpiece until the jaws are in the required position.

Sealing vessels and tissue bundles:

1. Open the jaws by pushing forward on the gray movable handle (**5**).
2. Grasp the intended vessel and/or tissue in the center of the jaws.

Warning

To avoid incomplete vessel sealing, do not grasp tissue beyond the electrode surface; do not place tissue in the jaw hinge.

3. Close the gray movable handle until it clicks and latches in place.
4. The instrument can be activated by either of the following two methods:
   - Press and hold the purple button (**8**) on the back of the instrument.
   - Depress and hold the round purple pedal (**3**) on the vessel sealing footswitch.

A continuous tone sounds to indicate that the vessel is being sealed. When the vessel sealing cycle is complete, a short end tone sounds and the generator discontinues RF output.

5. Release the purple instrument activation button or purple foot pedal when the seal cycle is complete.
6. If you choose to make a another seal adjacent to the existing seal, overlap on the edge of the existing seal.

Cutting tissue

Caution

Energy based devices, such as ESU pencils or ultrasonic scalpels, that are associated with thermal spread should not be used to transect seals.

1. Prior to cutting, the surgeon may inspect the vessel or tissue to ensure proper sealing.
2. To engage the cutting mechanism, pull the cutting trigger (**6**) completely back towards the body of the instrument until.
3. Open the jaws by squeezing the gray movable handle until it unlocks, then push it completely forward.

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Troubleshooting

Important

Keep the instrument jaws clean. Build-up of eschar may reduce seal and/or cutting effectiveness. Wipe jaw surfaces and edges with a wet gauze pad as needed.

During the sealing cycle, if the Regrasp indicator on the generator illuminates and a pulsed tone sounds, the generator automatically discontinues RF current.

1. Release the purple instrument button or purple footswitch pedal.
2. Open the jaws and inspect the tissue for a successful seal. Repeat the sealing procedure if necessary.

Possible regrasp or reseal indicator conditions include:

Instant Regrasp Indicator

- *Open circuit/High impedance detection* – Regrasp tissue and repeat procedure. If an instantaneous Regrasp condition continues, replace the instrument.

Delayed Regrasp Indicator

- *Pooled fluids around the instrument tip* – Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.
- *Thin tissue* – Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.
- *Grasping metal object* – Avoid grasping metal objects, such as staples or clips, in the jaws of the instrument.

Time Out Reseal Indicator

- *Maximum seal cycle time has been reached* – The generator needs more time and energy to complete the seal. Reactivate the seal cycle without removing or repositioning the clamp.

Important

The generator does not automatically shut off in the bipolar mode.

After Surgery

Discard the instrument after use.

tyco
Healthcare

DRAFT

EN Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.
Manufactured for Valleylab, a division of Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

BR Estéril, a menos que a embalagem tenha sido aberta ou danificada. Não reesterilize.
Fabricado para Valleylab, uma divisão da Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

DE Die Sterilität wird bis zum Öffnen der unbeschädigten Verpackung garantiert. Nicht wieder sterilisieren.
Hergestellt für Valleylab, ein Unternehmen der Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

ES Se garantiza la esterilidad a menos que se abra o se deteriore el en vase. No reesterilizar.
Fabricado para Valleylab, una división de Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

FR La stérilité du produit est garantie sauf si l'emballage est ouvert ou endommagé. Ne pas restériliser.
Fabriqué pour Valleylab, une division de Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

IT La sterilità è garantita a meno che la confezione non venga aperta o danneggiata. Non risterilizzare.
Prodotto per Valleylab, una divisione di Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

NL De steriliteit is gegarandeerd behalve wanneer de verpakking is geopend of beschadigd. Steriliseer niet opnieuw.
Gefabriceerd voor Valleylab, een divisie van Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

SE Sterilitetsgaranti gäller för obruten och oskadad steriförpackning. Sterilisera inte om.
Tillverkad för Valleylab, en avdelning inom Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA

RU Стерильность гарантируется при условии, что упаковка не была предварительно открыта или повреждена. Не стерилизуйте повторно.
Изготовлено для компании «Valleylab, подразделения Tyco Healthcare Group LP»
США, г. Боулдер, штат Колорадо, 80301-3299.

CN 在包装没有打开或损坏时，确保无菌。
为Tyco Healthcare Group LP 的下属企业 Valleylab
Boulder, CO 80301–3299 USA 制造

JP パッケージが開封されていたり、損傷がある場合を除き、無菌性は保証されます。
Tyco ヘルスケア・グループ LP の一部門であるバリーラブ社
Boulder, CO 80301-3299 USA のために製造

CE 0086

ИМО2

225 550 613

Tyco Healthcare UK Ltd., Gosport, PO13 0AS, UK

40

DRAFT

Unit Package Label

REF LS1500

LigaSure™

5 mm Sealer/Divider

225250126

STERILE EO

Rx ONLY

Single Use Only

Latex Free

Valleylab™

Valleylab
a division of Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA
Tyco Healthcare UK Ltd.
Gosport, PO13 0AS, UK

Made in USA

tyco / Healthcare

CE 0086

(01)20826233999997

EXP. DATE XXXX-XX

LOT XXXXXX

41

DRAFT

Case Label

Valleylab

Valleylab, a division of Tyco Healthcare Group LP
Boulder, CO 80301-3299 USA
Tyco Healthcare UK Ltd., Gosport, PO13 0AS, UK

Made in USA

tyco / Healthcare

STORAGE AND TRANSPORT PARAMETERS	
65°C -34°C	Relative Humidity: 0% - 75% noncondensing

Rx ONLY

Single Use Only

Latex Free

REF LS1500

(01)20826233999997

6 Units

STERILE EO

EXP. DATE

LigaSure™ 5 mm Sealer/Divider

XXXX-XX

Manufactured by
Valleylab
Made in USA
317000410

CE 0086

LOT XXXXXX

SECONDARY BARCODE

42

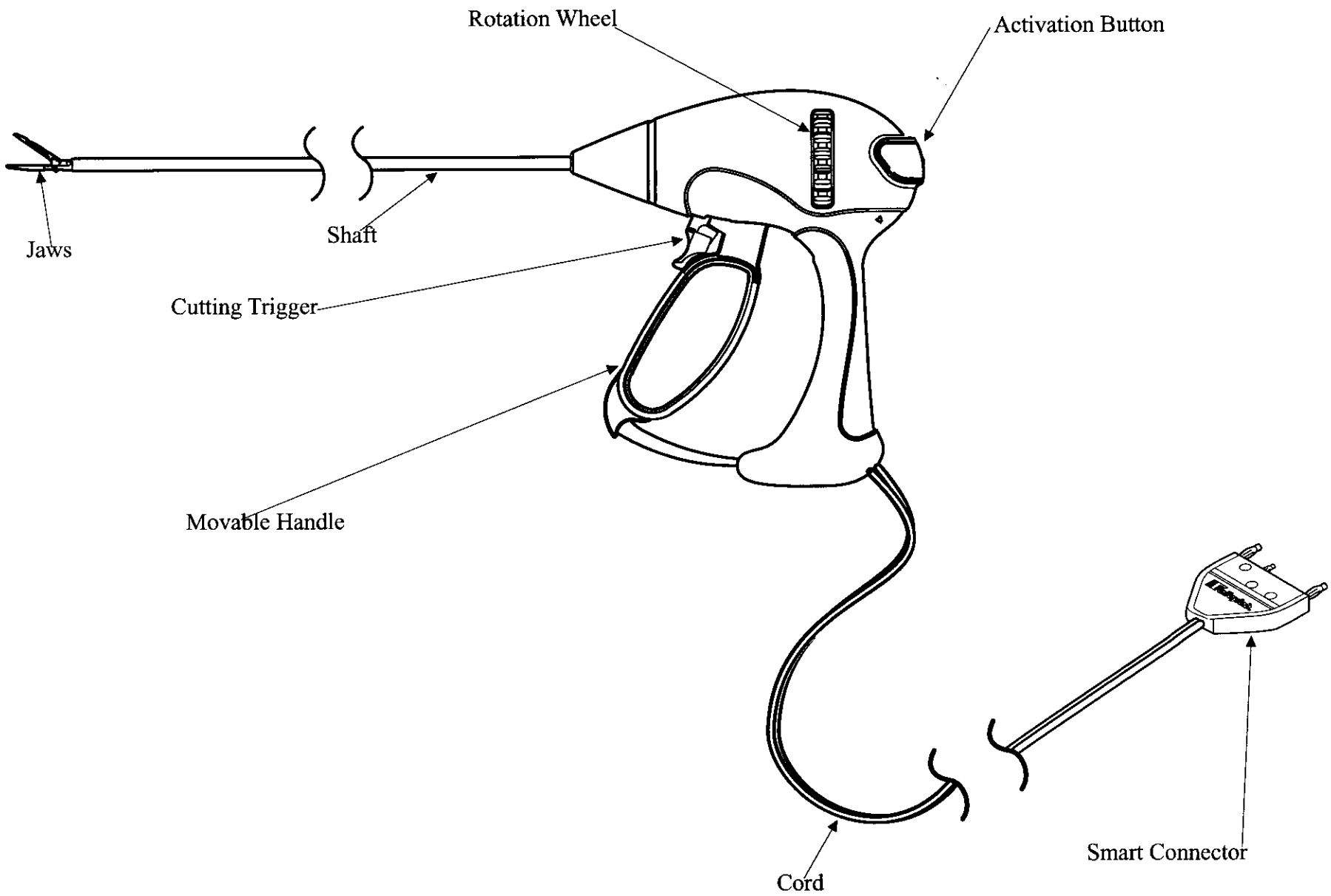
Attachment 4

PRODUCT ILLUSTRATION
LigaSure™ 5mm Laparoscopic Sealer-Divider

LigaSure 5mm Laparoscopic Sealer/Divider

CONFIDENTIAL

34



Attachment 5

MATERIALS BIOCOMPATIBILITY
LigaSure™ 5mm Laparoscopic Sealer-Divider

Materials Biocompatibility Testing Summary for Patient Contact Materials
LigaSure 5mm Laparoscopic Sealer-Divider

Component	Generic Material	Material Trade Name	Biocompatibility Testing
Rigid tube	304 Stainless steel	304 Stainless steel	Testing complete per ISO 10993-1
Rigid jaw	17-4 Stainless steel	17-4 Stainless steel (b) (4)	Testing complete per ISO 10993-1
Rigid jaw seal	Polycarbonate / Acrylonitrile-butadiene-styrene alloy	(b) (4)	Testing ongoing per ISO 10993-1
Pull tube	304 Stainless steel	304 Stainless steel	Testing complete per ISO 10993-1
Heat-shrink insulation	Polyester	(b) (4)	Testing complete per ISO 10993-1
Rotation wheel	Polycarbonate / Acrylonitrile-butadiene-styrene alloy	(b) (4)	Testing ongoing per ISO 10993-1
Overmolded moving jaw	Syndiotactic Polystyrene	(b) (4)	Testing complete per ISO 10993-1
Jaw stamping	17-4 Stainless steel	17-4 (b) (4)	Testing complete per ISO 10993-1
Jaw	17-4 Stainless steel	17-4 Stainless steel (b) (4)	Testing complete per ISO 10993-1
Jaw wire	Polytetrafluroethylene		Testing ongoing per ISO 10993-1
Jaw ceramic	Ceramic coating	(b) (4)	Testing complete per ISO 10993-1
Jaw pin	304 Stainless steel	304 Stainless steel	Testing complete per ISO 10993-1
Blade	440C Stainless steel	440C Stainless steel	Testing complete per ISO 10993-1
Lever	6/6 Nylon	(b) (4)	Testing ongoing per ISO 10993-1
Lever over-mold	Thermoplastic Elastomer	(b) (4)	Testing ongoing per ISO 10993-1
Lever latch (ski)	30% Glass-filled polyurethane	(b) (4)	Testing complete per ISO 10993-1
Ski pin	6/6 Nylon	(b) (4)	Testing ongoing per ISO 10993-1
Activation button	Polycarbonate	(b) (4)	Testing complete per ISO 10993-1
Handle (body)	Polycarbonate	(b) (4)	Testing complete per ISO 10993-1
Handle over-mold	Thermoplastic Elastomer	(b) (4)	Testing ongoing per ISO 10993-1

Window cover	Polycarbonate	(b) (4) [redacted]	Testing complete per ISO 10993-1
Cutter trigger	6/6 Nylon	(b) (4) [redacted]	Testing ongoing per ISO 10993-1
Pivot pin	Nylon 66	(b) (4) [redacted]	Testing complete per ISO 10993-1
Lubricating grease	Silicone Grease	(b) (4) [redacted]	Testing complete per ISO 10993-1

All materials are tested for the following per ISO 10993-1:

- Systemic Injection
- Intracutaneous toxicity
- Cytotoxicity
- Sensitization
- Hemolysis

Attachment 6

PRODUCT LITERATURE FOR PREDICATE DEVICES

- Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916)
- Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013)

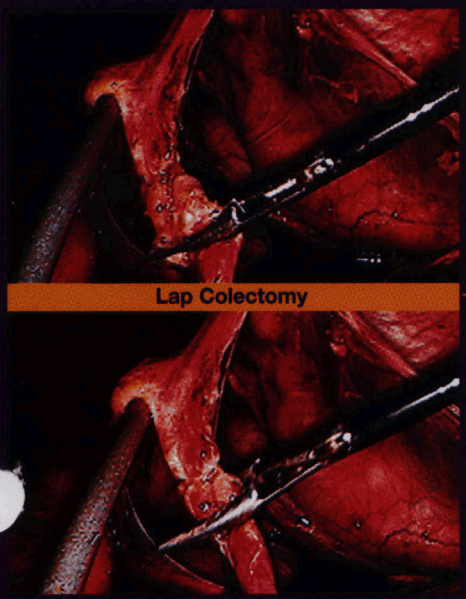
LigaSure™ Lap
essel sealing instrument

Providing BIG *Possibilities* in *Small Places*

The newly designed laparoscopic 5 mm instrument for sealing and fine dissection of structures in small surgical spaces.

- versatile grasping for multiple tissue types
- permanently fuses tissue bundles and vessels up to and including 7 mm in diameter without dissection
- average thermal spread approximately 2 mm

No matter what vein, artery, or tissue bundle you're likely to encounter in laparoscopic surgery, the LigaSure™ vessel sealing system can seal it.



Lap Colectomy

Valleylab™

49

LigaSure™ vessel sealing system

LigaSure™ Lap vessel sealing instrument

Benefits

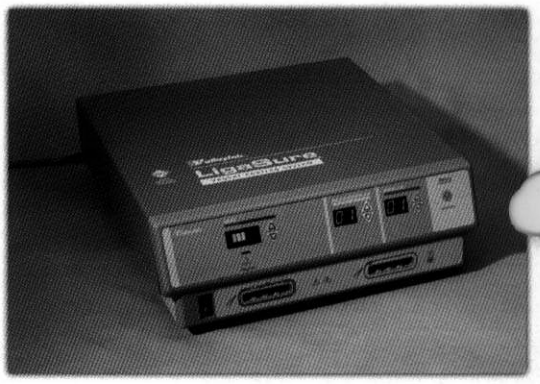
- Proven vessel sealing technology™ has provided permanent vessel fusion in over 220,000 procedures worldwide.
- Use with confidence on tissue bundles and vessels up to and including 7 mm in diameter without dissection or isolation.
- Valleylab's patented vessel sealing technology™ reforms the collagen in vessel walls and connective tissue into a permanent seal.
- A natural seal is created from the patient's own collagen, ensuring that the seal contains no foreign material.
- Generator feedback mechanism provides audible tone when seal cycle is complete – eliminating the guesswork.
- Visible translucent seal provides an indication of seal integrity, increasing surgeon confidence.
- Published clinical studies demonstrate seals withstand 3x systolic blood pressure.
- Minimal sticking, tissue charring, and reduced thermal spread, unlike standard bipolar and monopolar electrosurgery.
- Reduces the potential risk of needlestick injuries.

Procedures

- Adhesiolysis
- Appendectomy
- Colectomy
- Gastric Bypass
- Nissen Fundoplication
- Lap-Assisted Vaginal Hysterectomy
- Adrenalectomy
- Gastrectomy
- Splenectomy
- Salpingo-oophorectomy
- Nephrectomy

LigaSure LS1000 Specifications

Description	Specifications
Shaft Diameter	5 mm
Shaft Length	32 cm
Shaft Rotation	Continuous
Jaw Angle	Maryland Style
Seal Width	2 - 4 mm
Electrode Length	18 mm
Electrode Texture	Smooth Surface with Ceramic Stops



LigaSure™ Generator

Order Information

Catalog No.	Description	Quantity Order
LS1000	**LigaSure™ Lap single use laparoscopic device, 32 cm (12.6 in.)**	**6/case**
LS1100	LigaSure Atlas™ single use laparoscopic device, 37 cm (14.6 in.)	6/case
LS1200	LigaSure Precise™ single use instrument, 17 cm (6.5 in.)	6/case
LS2070	LigaSure™ Std reusable handpiece, 18 cm (7 in.)	1 each
LS2071	LigaSure™ Std single use snap-in electrode, compatible with LS2070	12/case
LS2110	LigaSure™ Axs reusable handpiece, 27 cm (10.5 in.)	1 each
LS2111	LigaSure™ Axs single use snap-in electrode, compatible with LS2110	12/case
LS3090	LigaSure™ Max reusable handpiece, 23 cm (9 in.)	1 each
LS3091	LigaSure™ Max single use snap-in electrode, compatible with LS3090	12/case
LS3110	LigaSure™ Xtd reusable handpiece, 28 cm (11 in.)	1 each
LS3111	LigaSure™ Xtd single use snap-in electrode, compatible with LS3110	12/case
LigaSure	LigaSure™ Generator with Instant Response™ technology	1 each
LS0200	Sterilizer case for reusable LigaSure™ handpieces	1 each

Valleylab
a division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301-3299 USA
800 255 8522

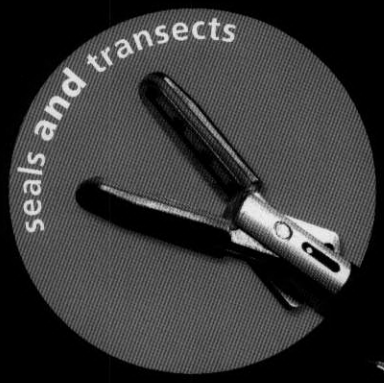
tyco / Healthcare

Valleylab™

Specifications subject to change without notice.

Printed in U.S.A. 945605238 2/02

LigaSure Atlas™
vessel sealing instrument

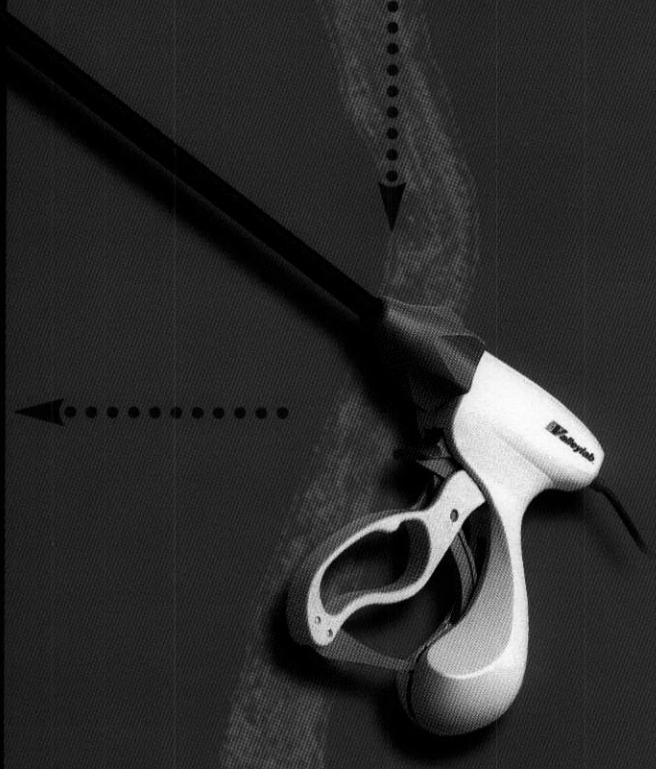


Providing *a world of* NEW Possibilities in *Laparoscopic Surgery*

The New LigaSure Atlas™ Laparoscopic Sealer/Divider Instrument

- versatile grasping for multiple tissue types
- permanently fuses tissue bundles and vessels up to and including 7 mm in diameter without dissection
- average thermal spread approximately 2 mm
- grasps and holds sealed tissue for easy transection

No matter what vein, artery, or tissue bundle you're likely to encounter in laparoscopic surgery, the LigaSure™ vessel sealing system can seal it.



Valleylab™

52

LigaSure™
vessel sealing system

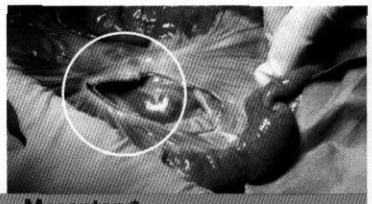
LigaSure Atlas™
vessel sealing instrument

Benefits

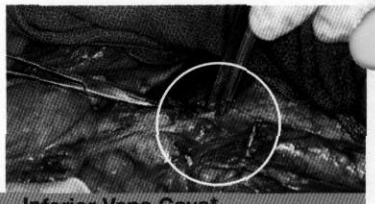
- Proven vessel sealing technology™ has provided permanent vessel fusion in over 220,000 procedures worldwide.
- Use with confidence on tissue bundles and vessels up to and including 7 mm in diameter without dissection or isolation.
- Valleylab's patented vessel sealing technology™ reforms the collagen in vessel walls and connective tissue into a permanent seal.
- A natural seal is created from the patient's own collagen, ensuring that the seal contains no foreign material.
- Generator feedback mechanism provides audible tone when seal cycle is complete – eliminating the guesswork.
- Visible translucent seal provides an indication of seal integrity, increasing surgeon confidence.
- Published clinical studies demonstrate seals withstand 3x systolic blood pressure.
- Minimal sticking, tissue charring, and reduced thermal spread, unlike standard bipolar and monopolar electrosurgery.
- Reduces the potential risk of needlestick injuries.

Procedures

- Adhesiolysis
- Appendectomy
- Colectomy
- Gastric Bypass
- Nissen Fundoplication
- Lap-Assisted Vaginal Hysterectomy
- Adrenalectomy
- Gastrectomy
- Splenectomy
- Salpingo-oophorectomy
- Nephrectomy


Mesentery*


Kidney*


Inferior Vena Cava*

*Animal Models

LigaSure Atlas™ Specifications

Description	Specifications
Shaft Diameter	10 mm
Shaft Length	37 cm
Shaft Rotation	<359 degrees
Jaw Angle	Straight
Seal Width	6 mm (2x 3 mm)
Electrode Length	22 mm
Electrode Texture	Smooth Surface with Ceramic Stops

Order Information

Catalog No.	Description	Quantity Order
LS1100	**LigaSure Atlas™ single use laparoscopic device, 37 cm (14.6 in.)**	**6/case**
LS1000	LigaSure™ Lap single use laparoscopic device, 32 cm (12.6 in.)	6/case
LS1200	LigaSure Precise™ single use instrument, 17 cm (6.5 in.)	6/case
LS2070	LigaSure™ Std reusable handpiece, 18 cm (7 in.)	1 each
LS2071	LigaSure™ Std single use snap-in electrode, compatible with LS2070	12/case
LS2110	LigaSure™ Axs reusable handpiece, 27 cm (10.5 in.)	1 each
LS2111	LigaSure™ Axs single use snap-in electrode, compatible with LS2110	12/case
LS3090	LigaSure™ Max reusable handpiece, 23 cm (9 in.)	1 each
LS3091	LigaSure™ Max single use snap-in electrode, compatible with LS3090	12/case
LS3110	LigaSure™ Xtd reusable handpiece, 28 cm (11 in.)	1 each
LS3111	LigaSure™ Xtd single use snap-in electrode, compatible with LS3110	12/case
LigaSure	LigaSure™ Generator with Instant Response™ technology	1 each
LS0200	Sterilizer case for reusable LigaSure™ handpieces	1 each

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5920 Longbow Drive
Boulder, CO 80301-3299 USA
800 255 8522

tyco / Healthcare

Valleylab™

Specifications subject to change without notice.

Printed in U.S.A. 945605230 52 2/02

Attachment 7

SUMMARY OF SAFETY AND EFFECTIVENESS
LigaSure™ 5mm Laparoscopic Sealer-Divider

K031011

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider

1. Submitter Information

Valleylab, Inc.
5920 Longbow Drive
Boulder, CO 80301
Contact: Herbert Vinson
Telephone: 303-530-6469

Date summary prepared: March 11, 2003

2. Name of Device

Trade or Proprietary Name: LigaSure™ 5mm Laparoscopic Sealer-Divider

Common Name: Bipolar Laparoscopic Electrosurgical Instrument

Classification Name:
- Electrosurgical Cutting and Coagulation Device and Accessories, and
- Gynecologic Electrocautery and Accessories

3. Predicate Devices

The Valleylab LigaSure™ 5mm Laparoscopic Sealer-Divider is substantially equivalent to the Valleylab LS1000 LigaSure™ LAP Laparoscopic Instrument (K981916), and the Valleylab LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument (K010013). All three of these devices are used in laparoscopic surgery to seal vessels by the application of RF energy to the vessels and tissues interposed between the jaws of the instrument. The LigaSure™ 5mm Laparoscopic Sealer-Divider and the LS1100 LigaSure ATLAS™ Laparoscopic Sealer-Divider Instrument divide tissue using a surgeon-actuated blade.

4. Device Description

The LigaSure 5mm Laparoscopic Sealer-Divider is a multi-functional electrosurgical instrument for use with the LigaSure Vessel Sealing Generator (K981916) when performing laparoscopic surgery. The instrument is capable of sealing vessels, dividing vessels and tissue clamped between its jaws, grasping tissue, and blunt dissection. The outer diameter of the instrument shaft is 5mm,

with a working length of 37 cm. Controls are located on the instrument handle. All controls can be operated with either the right or left hand.

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

5. Intended Use

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

Indications for use include general laparoscopic surgical procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure 5mm Vessel Sealer-Divider 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 Vessel Sealer-Divider can be used on vessels up to and including 7mm diameter, and tissue bundles as large as will fit in the jaws of the instrument.

6. Summary of Technological Characteristics

The LigaSure™ 5mm Laparoscopic Sealer-Divider has the same basic technological characteristics as the predicate devices noted above.

7. Performance Data

Performance testing and pre-clinical studies were performed to ensure that the LigaSure™ 5mm Laparoscopic Sealer-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

Memorandum

From: Reviewer(s) - Name(s) GEORGE J. MATTAMAL

Subject: 510(k) Number K03/011

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices. (SE)
- ☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☐ NO

- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

GEI & class II
[21CFR 878.4400]

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☐ NO

CP-N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 da

Predicate Product Code with class:	Additional Product Code(s) with panel (optional):
79 GEI & class II	79 GEI & class II

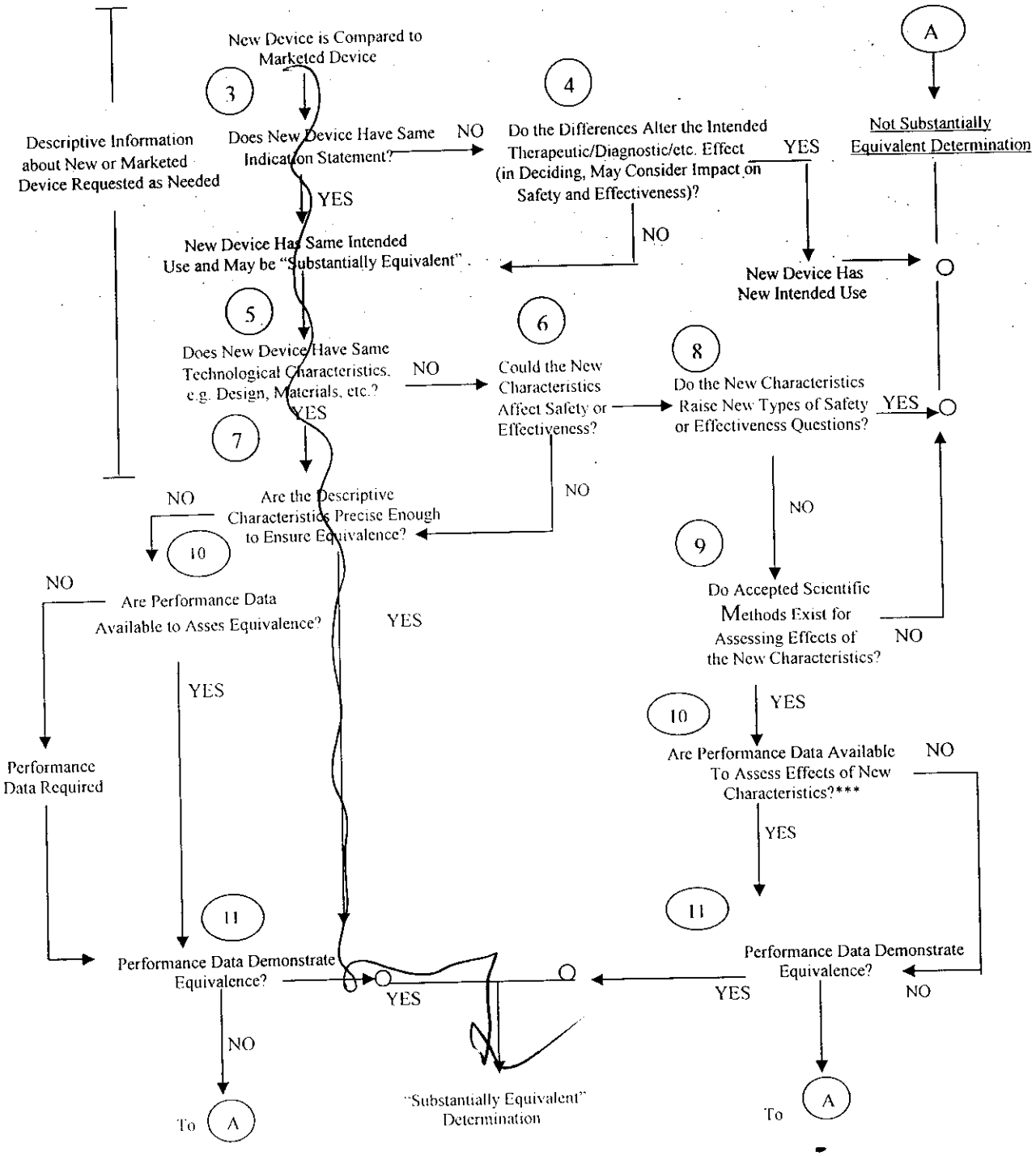
Review: Mil R P Ogl (Branch Chief) (GSDD) (Branch Code) 5/22/03 (Date)

Final Review: Miriam C. Provost for (Division Director) 5/28/03 (Date)

Revised:8/17/99

4

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 031011

Reviewer: GEORGE J. MATTAMAL

Division/Branch: DCRND / CSDB

Device Name: LS 1500 LIGASURE 5mm Lap. Seals - Dwdw.

Product To Which Compared (510(K) Number If Known): K981916 & K010013

	YES	NO	
1. Is Product A Device	Y		If NO = Stop
2. Is Device Subject To 510(k)?	Y		If NO = Stop
3. Same Indication Statement?	Y		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	Y		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	Y		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6a

MEMO TO THE RECORD
510(k) REVIEW
K031011

DATE: May 23, 2003 **OFFICE: HFZ-410**
FROM: Polymer Chemist **DIVISION: DGRND/GSDB**

DEVICE NAME: LigaSure™ 5mm Laparoscopic Sealer-Divider

COMPANY NAME: ValleyLab, Inc.

CONTACT: Mr. Herbert Vinson, Regulatory Associate
(Tel. 518-743-9272 and Fax. 518-743-9372).

DEVICE DESCRIPTION and PERFORMANCE: The sponsor has submitted the above referenced K031011 submission to notify FDA that their company intends to **modify** their previously cleared predicate devices, 1) LS1000 LigaSure™ Lap Laparoscopic Instrument, (K981916), and 2) LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013). Specifically, the **modifications** to the predicate device are the following:

- The predicate LS 1100 (K010013) has a surgeon-actuated **cutter to divide tissue** interposed in the jaws of the instrument and **working length of 37 cm** and the predicate LS1000 (K981916) has a **working diameter of 5mm** (please see the table 5, page 10 of the submission).

- The sponsor now intends to incorporate **these modifications** (cutting technology, working length of 37cm, working diameter of 5mm) into the new subject device, the "LigaSure™ 5mm Laparoscopic Sealer-Divider".

Other that this, the subject "LigaSure™ 5mm Laparoscopic Sealer-Divider (LS1500)" is **exactly same as** the predicate devices: 1) LS1000 LigaSure™ Lap Laparoscopic Instrument, (K981916), and 2) LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013). And the subject LS1500 device, as its predicates, is a sterile, single use electrosurgical device. It is a multifunctional device capable of vessel sealing, blunt dissection, grasping, and dividing tissue that is enclosed within its jaws. It is intended to be used as its predicates K981916 & K010013, in conjunction with an electrosurgical generator for delivery of radiofrequevcy current such as the sponsor's LigaSure™ Vessel Sealing Instrument (K981916). Specifically, the device is a bipolar electrosurgical instrument intended for use in general surgical and gynecologic laparoscopic procedures where the instrument creates a seal by application of bipolar electrosurgical RF energy to vascular structures (vessels) interposed between the jaws of the device. A blade is actuated for division of tissue.

The outer diameter of the subject LS1500 LigaSure™ 5 mmLaparoscopic Sealer Divider's shaft is 5mm, with a working length of 37 cm. The controls on the handle consist of a rotation knob, knife trigger and front lever. The rotation knob, located at the distal end of the handle, allows for up to

7

359 of rotation of the electrode jaws to improve visibility of the tissue as well as permit access to tissues on differing planes. The knife trigger is located close to the rotation knob and operates only when the jaws are closed and actuation of the knife pushes a blade through tissue enclosed in the jaws. Once released the tigger allows the knife to return. The front lever and the handle include a latching mechanism **(please see the representative drawing of the instrument, Attachment 4)** to control the applied pressure at the electrodes (jaws).

The sponsor has provided engineering drawings with photos and physical and general specifications of subject device. Also, the sponsor has provided a substantial equivalence comparison report with a side by side comparison describing device's intended use, physical characteristics (such as shaft length, jaw width, handle height, etc.), sizes, design, materials, specifications, Sizes of the vessels sealed, mean seal burst pressure, and other performance characteristics, etc. of the subject "LS1500 LigaSure™ 5 mmLaparoscopic Sealer Divider and its predicate devices, the sponsor's ValleyLab LS1000LigaSure™ Vessel Sealing Instrument (K981916),and LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013). The subject device is very similar to the predicate devices.

The sponsor has performed a battery of the following performance functional testing on the prototype LS1500LigaSure™ Laparoscopic Sealer Divider as it compared to the predicate devices' specifications:

Bench testing (Burst Strength and Thermal Spread): Performance verification (bench) testing was performed in order to evaluate and compare the sealing capabilities of the subject device and the predicate LS1000LigaSure Standard Instrument (K981916), and LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013). Testing included busrt pressure assessments and a rating of vessel seal quality. Excised porcine renal arteries were used for this study due to similarity in size and composition to humans. The arteries were categorized into three size ranges: Less than 0-2.0mm, 2.1- 4.0mm; and 4.1 to 7.0mm. Each instrument was used to seal approximately 48 vessels, at least 12 in each artery size range. Thus Vessels were sealed and divided. Thermal spread and seal burst strength were determined. Thermal spread is visible as a blanching of tissue adjacent to the seal area. Burst strength is determined by pumping water into each vessel at a constant rate until failure. . The test results demonstrated that the subject Sealer Divider to be similar in burst in seal quality to predicate K981916 and K010013 devices. For example, as shown below, burst strength and thermal spread comparison data for subject LS1500, and its predicate LS100, and LS1100 are as follow:

Burst Strength and Thermal Spread

Device	**Av. Thermal Spread (mm)**	**Average Burst Pressure (mmHg)**	**Burst Pressure Range (mmHg)**	**Probability of Burst Pressure 360mmHg or Greater**
LS1500	**1.40**	**1037**	**385 -1700**	**97%**
LS 1000	<2.0	1035	0 – 3313	>87%
LS1100	<2.0	1050	285 – 1700	>93%

Note that the calculated average thermal spread for subject LS1500 is 1.40mm and the calculated probability of obtaining a seal with a burst pressure of 360mmHg or greater with the device is 97%.

Pre-Clinical Testing: With regard to live tissue testing, the following pre-clinical testing was performed on canines to gather additional safety and performance data on the subject device and compared its performance with predicates, the LS1000 and LS1100. Acute and Chronic animal studies. According to the sponsor, the canine model was chosen for all these studies because of the similarity of the vessel size and anatomical location to humans. Forty-eight (48) individual vessels (arteries and veins) and tissue bundles across the size range 1.5 –7.6 mm were sealed using LS1500. Additionally, 10 seals were made with the LS1000 and 12 with LS1100. The results of the studies demonstrated that no bleeding occurred through any of the seals with any of the instruments, and in each instance, bleeding stopped immediately by spontaneous coagulation. .

Seal Quality Assessment: During the course of the performance verification and preclinical studies, the seal quality achieved by the subject device and predicate devices was characterized and addressed in the draft Instructions for Use form.

In summary, the results of the pre-clinical testing demonstrated that the subject device, LS1500 LigaSure™ 5mm Laparoscopic Sealer Divider, to be similar in seal quality, acute and chronic hemostasis, and cutting ability to the predicates, the LigaSure Standard Instrument (K981916), and the LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013).

- **Electrosurgical Testing:** The sponsor has certified that the subject device has been designed to conform to the applicable sections of the following standards:
    - IEC 60601-1 (1995), Medical Electrical Equipment Part 1: General Requirements for Safety,
    - IEC 60601-2-2 (1998-09), Medical Electrical Equipment Part 2: Particular Requirements for Safety of High Frequency Surgical Equipment, and
    - ANSI/AAMI HF 18, Electrosurgical Devices Standards.
- ***Biocompatibility Testing***: There are no biocompatibility issues associated with the device, since all the components of the device are constructed from the predicate K981916 and K010013 devices. Also, the sponsor has performed a battery of the following biocompatibility testing on the body contacting device component materials according to ISO-10993-1, Biological Evaluation of Medical Devices, Part 1-Guidance on Selection of Tests, Device Category "External Communicating Device, Blood Path Indirect, Contact Duration A":
    - Systemic Injection,
    - Intracutaneous Toxicity,
    - sensitization,
    - Hemolysis,
    - Cytotoxicity Test

The test results adequately demonstrated that the subject body contacting materials were non-toxic, non-irritating, and non-cytotoxic. There is no safety concern with this proposed device.
INTENDED USE/INDICATIONS FOR USE: The subject device, LS1500 LigaSure™ 5mm Laparoscopic Sealer Divider, a sterile, single use device, is a bipolar electrosurgical instrument intended for use with the LigaSure Generator (K981916) "in general surgical and gynecologic laparoscopic procedures where ligation and division of vessels is desired. The instrument creates a seal by application of bipolar electrosurgical RF energy to vascular structures (vessels) interposed between the jaws of the device A blade is actuated for division of tissue".

"The indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc."

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

The 1500LigaSure 5mm Laparoscopic Vessel Sealer Divider can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instrument".

This claim is SE (**Chart 3**) to predicate devices, the sponsor's ValleyLab 1100LigaSure™ Vessel Sealing Instrument (K981916), and the LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013).

PREDICATE DEVICE (S): The subject device is SE (**Chart 3**) in design configuration, technological characteristics (**Chart 5**), function, and intended use to its predicate devices, in particular to predicate devices, the sponsor's ValleyLab1100LigaSure™ Vessel Sealing Instrument (K981916), and the LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013).

STERILITY, PACKAGING, and LABELING: The proposed 1500LigaSure™ 5mm Laparoscopic Sealer Divider will be provided sterile and single use. The sponsor has stated that the device is designed to validate for Ethylene Oxide Sterilization method. The device will be sterilized in accordance with validated and periodically audited sterilization procedures using the "overkill" method, according to ANSI/AAMI/ISO Standard 11135-1994 as its method described in the AAMI National Standards and Recommended Practice for Ethylene Oxide Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. EtO decay curves are determined to ensure that residuals are at safe levels prior to product release. All products sterilized by EtO will have appropriate release limits for EtO and associated residuals as listed in ANSI/AAMI/ISO guidance 10993 - 7: 1995, "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residents". According to the sponsor, bioburden monitoring of the manufacturing area and of the finished product is performed on an ongoing basis, and the sterilization cycle is to be determined and validated to achieve a SAL of 10^{-6}.

The sponsor has provided FDA with an Intended Use Statement, and a 510 (k) summary of safety and effectiveness information. In the Draft labeling, the contraindication regarding contraceptive ***tubal coagulation (permanent female sterilization)*** has been made as a warning within IFU and also is incorporated the same to the **Indications for Use** statement. The rationale is that these modifications will now explicit as to the range of use and warning regarding female sterilization. And the Draft Labeling contains instructions for use of bipolar instruments, etc., and necessary warning and caution statements per "**the Guidance Document for General Surgical Electrosurgical Devices**". And the Draft Labeling is found to be satisfactory.

SAFETY AND EFFECTIVENESS INFORMATION & TRUTHFUL AND ACCURATE STATEMENT: The sponsor has provided 1) a summary of safety and effectiveness information and 2) a truthful and accurate statement about the device.

RECOMMENDATION: The subject "LigaSure™ Laparoscopic Sealer Divider" is SE (**Chart 7**) to its predicates, in particular to the sponsor's ValleyLab1100LigaSure™ Vessel Sealing Instrument (K981916), and the LS1100 LigaSure ATLAS™ Laparoscopic Instrument (K010013) It is associated with electrosurgical surgery and is categorized as 79 GEI (Electrosurgical Device, Cutting & Coagulation & Accessories), and the device is Class II based on 21 CFR 878.4400.

George J. Mattamal 5/24/03

George J. Mattamal, Ph.D. (Date)
General and Surgical Devices Branch
Division of General, Restorative, and Neurological Devices

OK Mil 5/27/03

CONTACT HISTORY: On 5/23/03, the sponsor (**Mr. Herbert Vinson**) was contacted in order to learn more about the device.

Concur
MP 5/28/03

11