

JAN 21 1999

K983743

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**BiSure™ Laparoscopic Bipolar Forceps**

**I. Submitter Information**

Valleylab, Inc.  
5920 Longbow Drive  
Boulder, CO 80301

Contact: Jack Rogers

Telephone: (303) 530-6172

Fax: (303) 530-6313

**II. Date Prepared**

October 22, 1998

**III. Name of Device**

Proprietary Name: BiSure™ Laparoscopic Bipolar Forceps

Common Name: Laparoscopic Bipolar Forceps

Classification Name: Electrosurgical Cutting & Coagulation and Accessories

**IV. Predicate Device**

Olympus Bipolar Forceps (K955623)

**V. Device Description**

The BiSure™ Laparoscopic Bipolar Forceps is a coagulating forceps device that is intended for laparoscopic use. Coagulation is achieved under laparoscopic visualization by applying electrosurgical energy to the forceps. The device is intended for use with bipolar outputs of compatible electrosurgical generators.

The device is comprised of a handle, inner and outer shafts, interchangeable forceps (electrodes), and connecting cable.

## **VI. Intended Use**

The BiSure™ Laparoscopic Bipolar Forceps is intended for use during laparoscopic bipolar coagulation.

## **VII. Summary of Technological Characteristics**

The device is identical to the *Olympus Bipolar Forceps (K955623)*, a legally marketed device, in design, function, and component composition, except for the following changes made to non-patient contacting portions:

- The release (used when connecting or changing the forceps) and rotation (used to rotate the forceps) mechanism has been changed to incorporate both functions into a one button (knob) design on the handle. The forceps may be rotated up to 120 degrees by pushing the release/rotation knob side-to-side as much as 60° either direction from its vertical position.
- The grip portion of the handle has been re-shaped. The grip incorporates a U-shaped stainless steel spring-action mechanism similar to the predicate device.

All patient-contacting components (forceps and shafts) of the device are identical to the *Olympus Bipolar Forceps* in design, function, and composition. Lengths of shafts for both devices are the same (330 mm and 450 mm) and the O.D. of the outer shaft is the same (5 mm).

## **VIII. Performance Data**

Performance testing has been performed to verify that the device functions as intended and that design specifications have been satisfied.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 21 1999

Mr. Jack Rogers  
Regulatory Affairs Associate  
Valleylab  
5920 Longbow Drive  
Boulder, Colorado 80301

Re: K983743  
Trade Name: BiSure™ Laparoscopic Bipolar Forceps  
Regulatory Class: II  
Product Code: GEI  
Dated: October 22, 1998  
Received: October 23, 1998

Dear Mr. Rogers:

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 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.

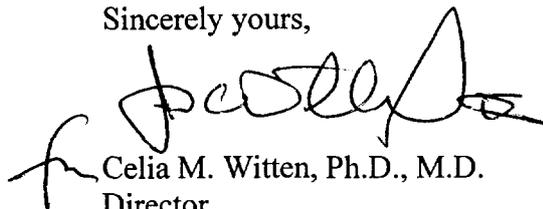
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

Page 2 - Mr. Jack Rogers

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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke 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

Enclosure

**INDICATIONS FOR USE**

510(k) Number (if known):     K983743    

Device Name: BiSure™ Laparoscopic Bipolar Forceps

Indications For Use:

The BiSure™ Laparoscopic Bipolar Forceps is indicated for use during laparoscopic bipolar coagulation.

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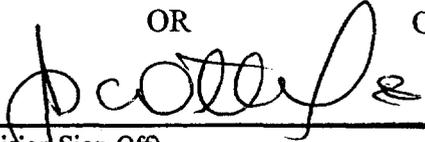
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
(Per 2.1 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number     K983743