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510(k) Summary for the Lumenis VersaCut™ Tissue Morcellator System

The 510(k) Summary is submitted in accordance with 21 CFR §807.92.

Submitters Name: Lumenis, Inc.

Submitters Address: 2400 Condensa Street
Santa Clara, CA 95051

Telephone: 408-764-3604
TeleFAX: 408-764-3934

Contact Person: Martha Murari, Ph.D.

Date Prepared: March 11, 2005

Device Trade Name: Lumenis VersaCut™ Tissue Morcellator System

Device Common Name: Soft Tissue Morcellator and Accessories

Device Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Device Classification: Class II

Predicate Devices: Coherent Tissue Morcellator Kit (K980079, concurred April 9, 1998)

Device Description:

The VersaCut™ Tissue Morcellator System is a multiple-use electrosurgical cutting and aspiration device that is intended for the morcellation and removal of dissected tissue under direct or endoscopic visualization. The cutting action of the VersaCut™ Tissue Morcellator System is driven by the motor in the handpiece and the treatment site is accessed through the sheath of a nephroscope using the endoscope adapter as needed to keep the cutting blades in the field of view. The VersaCut™ Tissue Morcellator System is comprised of main components as listed below. These main components are available separately when replacements are needed.

- Reusable, steam sterilizable handpiece (motor-body unit) with power cable
- Limited reuse, steam sterilizable cutting blade sets
- Reusable, steam sterilizable endoscope adapters
- Reusable aspiration pump–control unit combination with main power cable and fuses
- Reusable, multi-position, multi-staged footswitch with power cable
- Sterile, single use aspiration tubing
- Reusable sterilization tray, including cleaning brushes

The VersaCut™ Tissue Morcellator System is provided as a production-cleaned, non-sterile device. Before use in a sterile procedure, the handpiece, blade set(s), and endoscope adapter(s) are to be enzymatically-cleaned and steam-sterilized. Sterile aspiration tubing is provided with the device.

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Indications for Use:

The Lumenis VersaCut™ Tissue Morcellator System is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited.

Rationale for Substantial Equivalence:

The VersaCut™ Tissue Morcellator System has the same intended use / indications for use and same operating principle and technology (no change to the reciprocating action as the operational mode for the cutting blades) as the predicate device, Tissue Morcellator Kit. In addition, the devices have similar design features, components, and materials.

Safety and Effectiveness Information:

Physical testing was conducted to demonstrate performance of the Lumenis VersaCut™ Tissue Morcellator System in accordance with product specifications. Component materials intended for direct patient contact or having the potential for limited/indirect contact were demonstrated to have acceptable biocompatibility. Sterilization validation was repeated to support the modifications described.

Conclusion:

The VersaCut™ Tissue Morcellator System as modified by changes submitted is substantially equivalent to the predicate device, Tissue Morcellator Kit (K980079, concurred April 9, 1998). The devices have the same intended use / indications for use, same operating principle, and technology. The devices have similar design features, components, and materials. Results of *in vitro* bench testing demonstrate acceptable performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Martha Murari, Ph.D.
Senior Regulatory Affairs Associate
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K050639
Trade/Device Name: VersaCut™ Tissue Morcellator System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 11, 2005
Received: March 14, 2005

Dear Dr. Murari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050639

Device Name: Lumenis VersaCut™ Tissue Morcellator

Indications for Use:

The Lumenis VersaCut™ Tissue Morcellator System is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparoscopic, percutaneous, and open surgical procedures whenever access to the surgical site is limited.

Prescription Use _☒_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _☐_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050639

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

510(k) Number