LUMENIS®

MAY 1 3 2014

510(K) SUMMARY

VersaCut + Tissue Morcellator

510(k) Number K_____

Applicant's Name: Lumenis Ltd.
6 Hakidma Street
P.O.Box 240
Yokneam Industrial Park
Yokneam, 2069204, ISRAEL
Tel: +972-4-9599000
Fax: +972-4-9599050

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Common Name Soft Tissue Morcellator and Accessories

Trade Name: ***VersaCut + Tissue Morcellator***

Device Type: Soft Tissue Morcellator and Accessories

Preparation Date: October 20, 2013

Classification: **Regulatory Name:** Endoscope and accessories
Product Code: GCJ
Regulation No: 21 CFR 876.1500
Class: II
Classification Panel: Gastroenterology Urology devices

Device Description:

LUMENIS®

The ***VersaCut + Tissue Morcellator*** system is a multiple-use electrosurgical cutting and aspiration device that provides rapid and efficient morcellation and removal of dissected tissue under direct or endoscopic visualization. The cutting action of the ***VersaCut + Tissue Morcellator*** 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*** is comprised of a main component as listed below:

- Control unit with aspiration pump
- Limited reuse, steam sterilizable handpieces (motor-body unit) with power cable
- Limited reuse, steam sterilizable cutting blade sets
- Reusable, steam sterilizable endoscope adapters
- Drainage tube, single use
- Reusable, multi-position, multi-staged footswitch with power cable
- Sterile, single use aspiration tubing
- Tissue collection kit components, single use
- Reusable sterilization tray, including cleaning brushes

The ***VersaCut + Tissue Morcellator*** is provided cleaned and non sterile. Before use, the handpiece, blades set and the endoscope adapters are to be cleaned and sterilized.

Intended Use Statement:

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

LUMENIS®

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
VersaCut Tissue Morcellator system	K050639	March 14 , 2005

Performance Standards

VersaCut + Tissue Morcellator was tested and complies with the following standards:

- AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices;
- AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers;
- ISO 14971-1:2009 Risk management for medical devices;
- ISO 10993-1:2009 Biological Evaluation of Medical devices Part1: Evaluation and testing;
- ISO 13485:2003 Medical device- Quality management system-Requirement for regulatory purpose;
- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care products - Moist Heat.

LUMENIS®

Performance Bench Testing

Performance testing demonstrated that the ***VersaCut + Tissue Morcellator*** is as safe and effective as the cleared predicate device.

Summary of Pre-Clinical and clinical study

The safety and efficacy of the ***VersaCut + Tissue Morcellator*** was shown by performance bench testing.

Lumenis believes that clinical studies are not needed to claim safety and efficacy of the device

Substantial Equivalence to Predicate Devices

The ***VersaCut + Tissue Morcellator*** is a modification of the Lumenis *VersaCut Tissue Morcellator System* (K050639).

The intended use of the ***VersaCut + Tissue Morcellator*** is identical to the intended use of its predicate.

Both the ***VersaCut + Tissue Morcellator*** and the FDA-cleared Lumenis *VersaCut Tissue Morcellator System* (K050639) are multiple-use electrosurgical cutting and aspiration device that provides rapid and efficient morcellation and removal of dissected soft tissue under direct or endoscopic visualization.

The structures, the materials and the dimensions of the ***VersaCut + Tissue Morcellator*** are identical to the predicate device.

The minor differences between the ***VersaCut + Tissue Morcellator*** and its predicate device are an addition of an Inverted Handpiece, addition of a disposable tissue collector container with a one way valve to prevent reverse direction aspiration and an additional warning and operating step in the Operation Manual (OP). These additions were done in order to avoid reverse direction aspiration. See the labeling section and the device Operator Manual (Attachment No. 2). Moreover, performance testing demonstrated that the ***VersaCut + Tissue***

LUMENIS®

Morcellator is as safe and effective as the predicate device. Thus, the ***VersaCut + Tissue Morcellator*** is substantially equivalent to Lumenis *VersaCut Tissue Morcellator System* (K050639).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Lumenis Ltd.
% Mr. Yoram Levy
Mr. Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500

Re: K133272
Trade/Device Name: Versacut + Tissue Morcellator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 19, 2014
Received: April 2, 2014

Dear Mr. Levy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133272

Device Name: *VersaCut + Tissue Morcellator*

Indications for Use: The ***VersaCut + Tissue Morcellator*** is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparascopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.

Prescription Use __X_____ (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)

Joshua C. Nipper -S