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

August 12, 2015

Lumenis Ltd.
Ms. Elissa Burg
Director of Regulatory Affairs & Quality Systems
Yokneam Industrial Park
Yokneam 2069204, Israel

Re: K151947
Trade/Device Name: LightSheer Desire Light Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 12, 2015
Received: July 15, 2015

Dear Ms. Burg:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151947

Device Name
LightSheer Desire Light Laser System

Indications for Use *(Describe)*
The LightSheer pulsed diode array laser systems are indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer pulsed diode array laser systems are intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Desire Light Laser System with LightSheer ET/XC Laser Handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, the treatment of Pseudofolliculitis Barbae (PFB). The LightSheer Desire Light Laser System with LightSheer ET/XC Laser Handpiece is also indicated for hair removal, permanent hair reduction* and the treatment of benign pigmented lesions and leg veins.

* Note: Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

LightSheer Desire Light Laser System

Applicant Name: Lumenis Ltd.
6 Hakidma Street PO Box 240
Yokneam Industrial Park,
Yokneam 2069204, Israel
Tel: +972-4-9599000
Fax: +972-4-9599046

Contact Person: Elissa Burg - Director of Regulatory Affairs & Quality Systems
Lumenis Ltd.

6 Hakidma Street PO Box 240
Yokneam Industrial Park,
Yokneam 2069204, Israel
Tel: +972-4-9599168
Fax: +972-4-9599198
Mail: Elissa.Burg@lumenis.com

Date Prepared: August 09, 2015

Trade Name: LightSheer Desire Light Laser System

Common Name: Pulsed Diode Array Laser

Classification Name: Powered laser surgical instrument

Product Code: GEX

Device Class: Class II

Regulation Number: 21 CFR 878.4810

Panel: General & Plastic Surgery

Predicate Device: LightSheer Duet Laser System, cleared under K053628.

Intended Use/ Indications for Use:

The LightSheer pulsed diode array laser systems are indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer pulsed diode array laser systems are intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Desire Light Laser System with LightSheer ET/XC Laser Handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, the treatment of Pseudofolliculitis Barbae (PFB). The LightSheer Desire Light Laser System with LightSheer ET/XC Laser Handpiece is also indicated for hair removal, permanent hair reduction* and the treatment of benign pigmented lesions and leg veins.

* Note: Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Modified Device Description:

The modified LightSheer Desire Light Laser System is a non-invasive aesthetic laser system that delivers pulsed infrared laser light with a wavelength ranging from 790-830 nm (805 nm nominal). The system consists of a laser console and two optional handpieces, ET or XC, which can be connected to the console, one at a time, via a universal plug-in connector and an umbilical cable.

The ET handpiece; delivers laser energy through a 9mm x 9mm tip up to 81 J maximum. The settings for this handpiece are selectable pulse duration from 5-400 ms, selectable fluency from 10-100 J/cm^2 and a pulse repetition rate up to 3 Hz maximum. The XC handpiece; delivers laser energy through a 12mm x 12mm tip up to 58 J maximum. The settings for this handpiece are selectable pulse duration from 5-400 ms, selectable fluency from 10-40 J/cm^2 and a pulse repetition rate up to 3 Hz maximum

The laser system delivers pulsed infrared laser light from the diode array in the ET or XC handpiece to the treatment area. In standard use, the handpiece is pressed against the patient's skin and a pulse of light is delivered. To initiate energy output, the system requires redundant activation of the handpiece enable button and the handpiece trigger button while the system is in the Ready mode.

The ET and XC handpieces include a chilled sapphire tip that is water-cooled to provide active skin cooling. The physician is able to control the settings of laser energy from the LCD display on the main console.

Substantial Equivalence

The intended use and indications for use of the LightSheer Desire Light Laser System are identical to the intended use and indications for use of its predicate device. In addition, the same technological characteristics and principles of operation apply for both systems. The modifications introduced to the subject LightSheer Desire Light Laser System as compared to the predicate system are designed and intended mainly for updating the system industrial design to form a table top console and increased user convenience.

Performance testing was conducted in order to demonstrate the performance of the LightSheer Desire Light Laser System and its substantial equivalence, with respect to the safety and effectiveness, to the cleared predicate system. The following activities were performed:

- Risk analysis activities in compliance with the requirements of ISO 14971.
- Electrical and laser safety and electromagnetic compatibility testing as required to conform to with the following performance standards:
  - EN 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- requirements and tests.
  - EN 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
  - EN 60601-2-22: Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.
  - EN 60825-1: Safety of laser products-Part 1: Equipment classification and requirements.
- Software verification and validation testing.
- Environmental testing demonstrating the ability of the subject system to withstand variant operation, storage and transportation conditions.
- System testing (e.g. handpieces use and authorization, treatment parameters, energy measurements, handpiece replacement, handpiece cooling, safety controls).

Test results indicated that the subject LightSheer Desire Light Laser System performs in accordance with its requirements and specifications, in similarity to its predicate device. Consequently, the LightSheer Desire Light Laser System was found to perform as well as its predicate, to be as safe and effective for its intended use as its predicate, and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.