



Food and Drug Administration  
10903 New Hampshire Avenue  
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September 18, 2017

Lumenis Ltd.  
Amaya Levie  
Head Of RA Surgical Bu  
6 Hakidma Street Po Box 240  
Yokneam, 2069204 IL

Re: K170179

Trade/Device Name: Lightsheer Desire; Lightsheer Desire Light; Lightsheer Duet;  
Lightsheer Infinity

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: August 17, 2017

Received: August 21, 2017

Dear Amaya Levie:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

**Jennifer R. Stevenson -S3**

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

## Indications for Use

510(k) Number (if known)

K170179

### Device Name

The LightSheer Family of Pulsed Diode Array Laser Systems (LightSheer Duet, LightSheer Desire, LightSheer Desire Light and LightSheer Infinity)

### Indications for Use (Describe)

#### LightSheer Duet:

The LightSheer Duet System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Duet System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Duet System with LightSheer ET 805nm Laser Handpiece is intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Hair removal, permanent hair reduction\*
- Treatment of benign pigmented lesions

The LightSheer Duet System with LightSheer HS 805nm Laser Handpiece is intended for:

- Treatment of benign vascular lesions
- Treatment of benign pigmented lesions
- Hair removal, and permanent hair reduction\*

#### LightSheer Desire:

The LightSheer Desire System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Desire System with LightSheer ET/XC 805nm Laser Handpieces are intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Hair removal, permanent hair reduction\*
- Treatment of benign pigmented lesions

The LightSheer Desire System with LightSheer HS 805nm Laser Handpiece is intended for:

- Treatment of benign vascular lesions
- Treatment of benign pigmented lesions
- Hair removal, and permanent hair reduction\*

The LightSheer Desire System with LightSheer ET/XC 1060nm and LightSheer HS 1060nm Handpieces are intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions
- Hair removal, permanent hair reduction\*
- Treatment for Pseudofolliculitis Barbae (PFB)
- Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
- Treatment of wrinkles

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LightSheer Desire Light:

The LightSheer Desire Light System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire Light System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Desire Light System with LightSheer ET/XC 805nm Laser Handpieces are intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Hair removal, permanent hair reduction\*
- Treatment of benign pigmented lesions

The LightSheer Desire Light System with LightSheer ET/XC 1060nm Handpiece is intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
- Hair removal, permanent hair reduction\*
- Treatment for Pseudofolliculitis Barbae (PFB)
- Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
- Treatment of wrinkles

LightSheer Infinity:

The LightSheer Infinity System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Infinity System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

The LightSheer Infinity System with LightSheer ET/LR 805nm Laser Handpieces is intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Hair removal, permanent hair reduction\*
- Treatment of benign pigmented lesions

The LightSheer Infinity System with LightSheer HS 805nm Laser Handpiece is intended for:

- Treatment of benign vascular lesions
- Treatment of benign pigmented lesions
- Hair removal, and permanent hair reduction\*

The LightSheer Infinity System with LightSheer ET/LR 1060nm and LightSheer HS 1060nm Handpieces is intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
- Hair removal, permanent hair reduction
- Treatment for Pseudofolliculitis Barbae (PFB)
- Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
- Treatment of wrinkles

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

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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)

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

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## 510(k) SUMMARY



Lumenis LightSheer Family of Diode Pulsed Array Laser Systems

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**Date Prepared:** September 14, 2017

**Trade Name:** Lumenis LightSheer Family of Diode Pulsed Array Laser Systems

**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:** K053628 Lumenis LightSheer Duet Light Laser System  
K151947 Lumenis LightSheer Desire Light Laser System  
K133319 LightSheer HS and ET 1060nm HPs for Duet

## **Indications for Use:**

### **LightSheer Duet:**

The LightSheer Duet System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Duet System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

- The LightSheer Duet System with LightSheer ET 805nm Laser Handpiece is intended for:
  - Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
  - Treatment of pseudofolliculitis barbae (PFB)
  - Hair removal, permanent hair reduction\*
  - Treatment of benign pigmented lesions
  
- The LightSheer Duet System with LightSheer HS 805nm Laser Handpiece is intended for:
  - Treatment of benign vascular lesions
  - Treatment of benign pigmented lesions
  - Hair removal, and permanent hair reduction\*

### **LightSheer Desire:**

The LightSheer Desire System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

- The LightSheer Desire System with LightSheer ET/XC 805nm Laser Handpieces are intended for:
  - Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
  - Treatment of pseudofolliculitis barbae (PFB)
  - Hair removal, permanent hair reduction\*
  - Treatment of benign pigmented lesions
  
- The LightSheer Desire System with LightSheer HS 805nm Laser Handpiece is intended for:
  - Treatment of benign vascular lesions
  - Treatment of benign pigmented lesions
  - Hair removal, and permanent hair reduction\*
  
- The LightSheer Desire System with LightSheer ET/XC 1060nm and LightSheer HS 1060nm Handpieces are intended for:

- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions
- Hair removal, permanent hair reduction\*
- Treatment for Pseudofolliculitis Barbae (PFB)
- Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
- Treatment of wrinkles

### **LightSheer Desire Light:**

The LightSheer Desire Light System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Desire Light System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

- The LightSheer Desire Light System with LightSheer ET/XC 805nm Laser Handpieces are intended for:
  - Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
  - Treatment of pseudofolliculitis barbae (PFB)
  - Hair removal, permanent hair reduction\*
  - Treatment of benign pigmented lesions
- The LightSheer Desire Light System with LightSheer ET/XC 1060nm Handpiece is intended for:
  - Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
  - Hair removal, permanent hair reduction\*
  - Treatment for Pseudofolliculitis Barbae (PFB)
  - Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
  - Treatment of wrinkles

### **LightSheer Infinity:**

The LightSheer Infinity System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The LightSheer Infinity System is intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

- The LightSheer Infinity System with LightSheer ET/LR 805nm Laser Handpieces is intended for:



- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions and leg veins
  - Treatment of pseudofolliculitis barbae (PFB)
  - Hair removal, permanent hair reduction\*
  - Treatment of benign pigmented lesions
- The LightSheer Infinity System with LightSheer HS 805nm Laser Handpiece is intended for:
- Treatment of benign vascular and pigmented lesions
  - Hair removal, and permanent hair reduction\*
- The LightSheer Infinity System with LightSheer ET/LR 1060nm and LightSheer HS 1060nm Handpieces is intended for:
- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.
  - Hair removal, permanent hair reduction
  - Treatment for Pseudofolliculitis Barbae (PFB)
  - Treatment of benign pigmented lesions, including age spots, solar lentigines, cafe-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions
  - Treatment of wrinkles

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

### **Device Description:**

The Lumenis LightSheer Family of Pulse Diode Array Laser Systems consists of four laser consoles that can be used with up to four different types of handpieces. The four laser consoles are: LightSheer Duet, LightSheer Infinity, LightSheer Desire, and LightSheer Desire Light. The laser consoles provide (1) a graphical user interface and software for control of the system, (2) the needed electronics to control and power the accessories, (3) handpiece connection port(s), (4) a vacuum pump (most models) and (5) cooling system.

Handpieces can be divided into two categories, depending on the technology applied to the skin during treatment: high speed (HS) Handpieces with vacuum technology (HIT™) or ET, XC and LR Handpieces with cooling technology (ChillTip), available with different sized tips. Some handpieces are universal, supporting different ChillTip sizes within a single handpiece. In addition, these handpieces either deliver pulsed diode laser light with wavelengths ranging from 790 - 950nm (805nm nominal) or 1040-1080nm (1060nm nominal), depending on the diode array type. The same LightSheer Handpieces are compatible with multiple systems (such as the LightSheer Duet, LightSheer Infinity, LightSheer Desire, and LightSheer Desire Light), in which case they differ only in terms of the mechanical connection to the console.

**Reason for Submission:**

The purpose of this 510(k) is to add the 1060nm handpieces to the LightSheer Desire and LightSheer Desire Light Systems. These handpieces have been previously cleared for use with other systems in the LightSheer Family of Pulse Diode Array Laser Systems. For completeness, this submission also includes a description of all four systems in the LightSheer Family of Pulsed Diode Array Laser Systems.

**Substantial Equivalence:**

The intended use and indications for use of the modified LightSheer Desire Laser and LightSheer Desire Light are identical to the intended use and indications for use of its predicate device LightSheer Duet. In addition, the same technological characteristics and principles of operation apply for these systems. The modifications introduced to the subject LightSheer Desire Laser and LightSheer Desire Light involve adding compatibility to LightSheer1060nm Handpieces that have been previously been cleared for use with the LightSheer Duet System. In addition, there have also been some modifications made to the systems since their last clearance. These modifications have undergone a contemporaneous regulatory analysis that concluded that the cumulative modifications could not significantly affect safety or effectiveness. Performance testing was also conducted in order to demonstrate the performance of the modified LightSheer Family of Pulsed Diode Array Laser Systems and to verify that no different questions of safety and effectiveness have been raised due to the modifications introduced. The following activities were performed:

- Risk analysis per ISO 14971.
- Electrical and laser safety and electromagnetic compatibility testing as required to conform to performance standards as follows:
  - 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
  - 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- requirements and tests
  - 60825-1: Safety of laser products -Part 1: Equipment classification and requirements
  - 60601-2-22: Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.
- Software verification and validation

Consequently, it is Lumenis' belief that the LightSheer Family of Pulsed Diode Array Laser Systems is substantially equivalent to its legally marketed predicates.