LUMENIS®
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MAR 2 0 2014

510(k) Summary: K133319

ET LightSheer 1060 and High Speed LightSheer 1060

Establishment Registration Number: 3004135191

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Trade Name: ET LightSheer 1060 and High Speed LightSheer 1060

Classification name: Powered laser surgical instrument

Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Common/Usual Name: Pulse Diode Array Laser

Product Code: GEX

Regulation No.: 878.4810

Class: II

Panel identification: General & Plastic Surgery

Predicate Devices:

LightSheer Duet Laser System from Lumenis Ltd, cleared under 510(k) K053628, the Family of Altus Medical CoolGlide Aesthetic Lasers from Altus Medical, Inc. (currently Cutera Inc.) cleared under 510(k) K022226, and the GentleMAX Family of Laser Systems from Candela Corporation cleared under 510(k) K112715.

Description of the device:

The ET LightSheer 1060 and High Speed LightSheer 1060 are two treatment handpieces, intended to be used with Lumenis LightSheer Duet Laser System.

One handpiece is the ET LightSheer 1060 handpiece, which delivers laser energy through a 9 x 9 mm tip up to 90 J maximum. The settings for this handpiece are selectable pulse duration from 5 – 400 ms, selectable fluence from 10 – 100 J/cm2 and a pulse repetition rate up to 3 Hz maximum.

The second handpiece is the High Speed LightSheer 1060 handpiece, which delivers laser energy from a 22 x 35 mm diode array up to 93 J maximum. The settings for this handpiece are pulse duration from 10 – 100ms, selectable fluence from 4.5 - 12 J/cm2 and multiple pulsing up to 3 pulses.

The ET LightSheer 1060 handpiece tip is water-cooled to provide active skin cooling. The High Speed LightSheer 1060 handpiece tip uses vacuum and lower laser energy densities which reduce skin heating.

Indications for Use:

ET LightSheer 1060 and High Speed LightSheer 1060 are intended for treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

ET LightSheer 1060 and High Speed LightSheer 1060 are intended for hair removal, permanent hair reduction, and the treatment for Pseudofolliculitis Barbae (PFB).

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.

ET LightSheer 1060 and High Speed LightSheer 1060 are intended for the treatment of benign pigmented lesions, including age spots, solar lentigines, café-au-lait spots, nevi of Ota/Ito, melasma, Becker's nevi and other benign pigmented lesions.

ET LightSheer 1060 and High Speed LightSheer 1060 are also intended for treatment of wrinkles.

ET LightSheer 1060 and High Speed LightSheer 1060 are intended for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.

Substantial Equivalence:

Technological Characteristics

ET LightSheer 1060 and High Speed LightSheer 1060 have the same intended use, principles of use and mechanisms of operation as Lumenis Ltd. treatment handpieces cleared under 510(k) K053628, and have equivalent performance characteristics. The materials used for ET LightSheer 1060 and High Speed LightSheer 1060, as well as the manufacturing methods, are identical to the devices cleared under 510(k) K053628. The difference resides in the wavelength of 1060nm for the proposed devices in comparison with 805nm for the cleared treatment handpieces. ET LightSheer 1060 and High Speed LightSheer 1060 have the same intended use and have equivalent performance characteristics as the Family of Altus Medical CoolGlide Aesthetic Lasers from Altus Medical, Inc. (currently Cutera Inc.) cleared under 510(k) K022226 and the GentleMAX Family of Laser Systems from Candela Corporation cleared under 510(k) K112715.

Testing

ET LightSheer 1060 and High Speed LightSheer 1060 conform to
IEC 60601-1 Medical Electrical Equipment- General Requirements for Safety,
IEC 60601-1-2 Medical Electrical Equipment- Electromagnetic Compatibility,
IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems,
IEC 60601-2-22 Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment, and
IEC 60825-1 Safety of laser products - Part 1: Equipment classification, and requirements.

Conclusion:

The evaluation of the ET LightSheer 1060 and High Speed LightSheer 1060 does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to its predicate device.

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

March 20, 2014

Lumenis Ltd.
Mr. Iman Khorshid
Director Regulatory Affairs & Quality Specialist
6 Hakidma Street
Yokneam Industrial Park
P.O. Box 240
Yokneam, 2069204 ISRAEL

Re: K133319
Trade/Device Name: ET LightSheer 1060 and High Speed LightSheer 1060
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: February 19, 2014
Received: February 24, 2014

Dear Mr. Khorshid:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Felipe Aguel

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

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)*
K133319

Device Name
ET LightSheer 1060 and High Speed LightSheer 1060

Indications for Use *(Describe)*
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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)

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

FOR FDA USE ONLY

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

Neil R Ogden -S
2014.03.13 12:21:35 -04'00' For BSA

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