APR

K053628

LUMENIS
Enhancing Life. Advancing Technology.

510(k) Summary

Applicant:	Lumenis, Inc
Address:	2400 Condensa Street Santa Clara, California 95051 USA
Contact Person:	Connie Hoy Global Director of Regulatory Affairs and Quality Assurance
Contact Numbers:	(408) 764-3303 Phone (408) 764-3500 Fax
Preparation Date:	December 28, 2005
Device Trade Name:	LightSheer® Duet™ Laser System
Common Name:	Pulsed Diode Array Laser
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see 21 CFR 878.4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	Lumenis, Inc. LightSheer® Pulsed Diode Array Laser System and AesThera Corporation AIP™ Intense Pulsed Light System.

Lumenis Inc.
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Santa Clara, CA 95051 USA
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t 800.635.1313
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System Description:

The LightSheer Duet Laser System is a non-invasive aesthetic laser. The system delivers pulsed infrared laser light with a wavelength ranging from 790 – 950 nm (800 nm nominal) and has two unique treatment handpieces. One handpiece is the LightSheer® ET™ 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 LightSheer® HS™ handpiece, which delivers laser energy from a 22 x 35 mm diode array up to 45 J maximum. The settings for this handpiece are pulse duration from 10 - 30 ms, selectable fluence from 3 – 5.2 J/cm2 and multiple pulsing up to 3 pulses.

The complete system consists of a console and two handpieces connected to the system by umbilical cables. 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 LightSheer ET handpiece tip is water-cooled to provide active skin cooling. The LightSheer HS handpiece tip uses vacuum and lower laser energy densities which reduces skin heating. The physician is able to control the settings of laser energy from the LCD display on the main console.

Intended Use of the Device:

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.

LightSheer® Duet™ Laser Systems with LightSheer® ET™ Laser Handpiece is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. The LightSheer® Duet™ Laser System with LightSheer® ET™ Laser Handpiece is also intended for hair removal, permanent hair reduction, and the treatment of benign pigmented lesions and leg veins.

LightSheer® Duet™ Laser Systems with LightSheer® HS™ Laser Handpiece is intended for the treatment of benign vascular and pigmented lesions, hair removal, and permanent hair reduction.

[redacted]

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Substantial Equivalence:

The specifications and indications for use of the LightSheer Duet Laser System are the same or very similar to those of the claimed predicate devices. The LightSheer Duet Laser System has the same or very similar indications for use for which the claimed predicates have been cleared. Based on the foregoing, the LightSheer Duet Laser System is substantially equivalent to the legally-marketed claimed predicate devices for the purposes of this 510(k) submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Lumenis, Inc.
c/o Ms. Connie Hoy
Global Director of Regulatory Affairs
and Quality Assurance
2400 Condensa Street
Santa Clara, California 95051

Re: K053628
Trade/Device Name: LightSheer® Duet™ 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: II
Product Code: GEX
Dated: March 1, 2006
Received: March 3, 2006

Dear Ms. Hoy:

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.

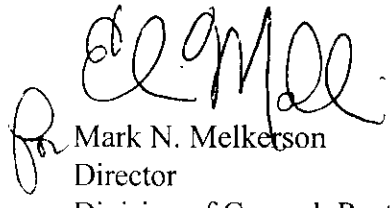
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
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): K053628

Device Name: LightSheer® Duet™ Laser System

Indications for Use:

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LightSheer® Duet™ Laser Systems with LightSheer® HS™ Laser Handpiece is indicated for the treatment of benign vascular and pigmented lesions, hair removal, and permanent hair reduction.

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)

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

510(k) Number K053628