JUN 1 9 2003

510(k) Summary

Table 1 - Administrative Information

Category:	Comments
Sponsor:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Correspondent:	Andrea L. Ruth, RAC Senior Associate II, Regulatory Affairs
Contact Numbers:	408.764.3235
Device Common Name	Laser Powered Surgical Instrument (and Accessories)
Device Proprietary Name	Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
Device Classification Name	Laser Surgical Instrument for Use in General and planstic Surgery and in Dermatology
Device Classification	21 CFR § 878.4810
Predicate Devices	IPL Quantum Family; VascuLight Family; Lyra™; GentleYAG™
Predicate Device Manufacturer(s)	Lumenis; Lumenis; LaserScope; Candela
Predicate Device Reference(s)	K020839; K020839; K020021; K022951
Predicate Device Classification Name(s)	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Predicate Device Classification(s)	21 CFR §878.4810

Date Summary Was Prepared: March 13, 2003.

Description of the Device: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems are comprised of the following main components:

* A light/laser system console (including software and control electronics);
* A control and display panel; and
* One or more attached hand-piece(s), which may have integrated skin cooling components.

Intended Use: The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are intended for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology.

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Table 2 - Comparison to Predicate Devices:

Predicate Device	This device	Lumenis VascuLight or IPL Quantum Families	Laserscope Lyra™	Candela GentleYAG
510(k) Reference	Current submission	K020839	K020021	K022951
Intended Use	Photocoagulation, photothermolysis and hemostsis See indications for use statement	Photocoagulation, photothermolysis and hemostsis	Treatment of facial wrinkles	Treatment of facial wrinkles
Device Description	IPL and IPL/Nd:YAG combination	Same	Nd:YAG	Nd:YAG
Output Energy Used	Coherent and non-coherent light	Same	Same	Same
Energy Configuration	515 – 1200 nm 1064nm	Same	1064 nm	1064 nm
Fluence	Up to 150 J/cm^2	Same	Up to 250 J/cm^2	10 to 70 J/cm^2
Pulse	2 to 16 ms (to 48 ms triple pulsed)	Same	10 to 50 ms	3 ms
Pulse Rate	0.33 Hz	Same	1-10 pps	1 Hz
Spot Size	6mm	Same	3mm, 5mm, 10mm	12 mm
Beam Delivery	Cooling Hand-piece	Same	Fiber w/cooling aiming beam sapphire crystal	Lens-coupled optical fiber with hand-piece
Electricity	115/230V	Same	115/230V	230V
Simultaneous Delivery?	No	No	No	No
Single Use?	No	No	No	No
Sterilized?	No	No	No	No
Manufacturer	Lumenis	Lumenis	LaserScope	Candela
Device Classification	II; 21 CFR § 878.4810, GEX	II; 21 CFR § 878.4810, GEX	II; 21 CFR § 878.4810, GEX	II; 21 CFR § 878.4810, GEX

Summary of the Clinical Data: Clinical data was provided to demonstrate that the Lumenis Family of IPL and IPL/Nd:YAG laser (1064 nm) systems are safe and effective, when indicated in specific applications in the medical specialties of general and plastic surgery, and dermatology.

Conclusion: The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems were shown to be substantially equivalent to the predicate devices cleared in K020839. The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems has identical intended use, as well as functional and design features as the currently marketed predicate devices. The only change is expansion of labeled indications for use, which fall within the scope of the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Ms. Andrea L. Ruth, RAC
Regulatory Affairs
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K024093
Trade/Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
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 13, 2003
Received: March 21, 2003

Dear Ms. Ruth:

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 CFR Part 807); labeling (21 CFR Part 801); 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.

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested by FDA

510(k) Number (if Known): K024093

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL / Nd:YAG Systems and the Real Time Chiller

Indications For Use:
The Lumenis Family of Intense Pulsed-Light (IPL) systems and combination IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

Intense Pulsed Light Energy/Wavelengths (515 - 1200 nm):

* The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars and striae;
* The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
* The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[1], hair reduction in skin types I-VI through selective targeting of melanin in hair follicles;

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1 Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

510(k) Number (if Known): K024093

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL / Nd:YAG Systems and the Real Time Chiller

Indications For Use: ***Continued from Previous Page***

Nd:YAG Laser Wavelength (1064 nm):

* The coagulation and hemostasis of vascular lesions and soft tissue, including:
  * Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 - 4.0 mm diameter) of the leg;
* The non-ablative treatment of facial wrinkles.

The Real Time Chiller is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

* Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
* Reduce discomfort during and/or associated with light or laser treatment;
* Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
* Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
* Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices