

Summary

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I. General Information **JUL 17 2003**

Submitter: Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051

Contact Person: Andrea L. Ruth,
Senior Associate, Regulatory Affairs

Summary Preparation Date: January 31, 2003

II. Names

Device Names: Lumenis Family of Intense Pulsed-Light (IPL) and
IPL/Nd:YAG Laser Systems

Primary Classification
Name: Laser Powered Surgical Instrument (and Accessories)

III. Product Description

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;
- * One or two attached hand-piece(s), which may have integrated skin cooling components.

IV. Indications for 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 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.

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

- * 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 permanent², hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

Nd:YAG Laser Wavelength (1064 nm) is indicated for 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 removal of unwanted hair from all skin types, and to effect stable long-term, or permanent², hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

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).

V. Rationale for Substantial Equivalence

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems share the same general indications for use, and therefore is substantially equivalent for use in surgical, aesthetic and cosmetic applications to the previously cleared IPL and IPL/Nd:YAG family.

VI. Safety and Effectiveness Information

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

² 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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specific applications in the medical specialties of general and plastic surgery, and dermatology.

VII. 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.



JUL 17 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K030342

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: May 12, 2003

Received: May 13, 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,


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

510(k) Number (if Known): K 030342

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

Indications For 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 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:

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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)

³ 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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Device Name: Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

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- * Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

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

510(k) Number K030342

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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