JAN 3 1 2005

Attachment 17
510(k) Summary for the K043173
Q-switched Nd:YAG Laser Treatment Head for the Lumenis Quantum Series

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Martha Murari, Ph.D. Senior Regulatory Affairs Associate Connie Hoy Global Director RA / QA
Summary Preparation Date:	November 15, 2004

II. Names

Device Names:	Q-switched Nd:YAG Laser Treatment Head for the Quantum Series
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Lumenis family of Intense Pulsed Light (IPL) and IPL/Nd:YAG laser systems (K020839, K030527, K024093, K030342) marketed by Lumenis.
- MedLite C^3- Q Switched Nd:YAG laser (K011677) marketed by Hoya ConBio (formerly Continuum Electro-Optics)
- Light-Age Q-Clear laser (K033259) marketed by Light Age Inc.
- Q-YAG 5 laser (formerly Clear Light)(K003460, K023967) marketed by Palomar Medical Technologies Inc.

IV. Product Description

The Lumenis Quantum series of IPL/Nd:YAG systems are intense pulsed-light (IPL) and Nd:YAG laser devices. Each Quantum system is comprised of three main components:

- A system console (including software and control electronics, key-operated power control switch, power-on indicator, emergency shut-off knob and a remote interlock connector);
- A control and display panel;
- One or more delivery handpiece(s), the Treatment Heads.

The Q-switched Nd:YAG Treatment Head for the Quantum series is a pulsed laser operating at a wavelength of 1064 nanometers. It is an upgrade that can be installed on any Quantum system.

The Q-switched Nd:YAG Laser Treatment Head is a hand held device comprised of the laser head and optics, trigger circuit, safety components and cooling circuit. The Q-switched Nd:YAG Laser Treatment Head is connected to the Quantum console via an umbilical cable and connector.

V. Indications for Use

The Q-switched Nd:YAG Laser Treatment Head for the Quantum series is intended for use in the medical specialties of plastic surgery and dermatology for applications requiring selective photothermolysis and photo-acoustic effects in target chromophores.

The Q-switched Nd:YAG Laser Treatment Head for the Quantum series is indicated for:

- Removal of dark tattoos
- Treatment of pigmented lesions

VI. Rationale for Substantial Equivalence

The Q-switched Nd:YAG Laser Treatment Head for the Quantum series shares the same indications for use as the predicate MedLite C^3 Q-switched Nd:YAG laser system (K011677), the Q-Clear laser system (K033259) and the Q-YAG 5 / Clear Light (K003460), in that the 1064 nm wavelength is indicated for:

- Removal of dark tattoos
- Treatment of pigmented lesions

The technical specifications of the Q-switched Nd:YAG Laser Treatment Head for the Quantum series are similar or identical to those of the predicate MedLite C^3 Q-switched Nd:YAG laser system (K011677), the Q-Clear laser system (K033259) and the Q-YAG 5 / Clear Light (K003460).

Therefore, the Q-switched Nd:YAG Laser Treatment Head for the Quantum series is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The Q-switched Nd:YAG Laser Treatment Head for the Quantum series shares the same indications for use, same principle of operation, same wavelength, same or similar fluence range and spot sizes as the predicate devices. A Clinical Evaluation Report demonstrated the safety and effectiveness of the Q-switched Nd:YAG laser for the claimed indications for use. The Q-switched Nd:YAG Laser Treatment Head for the Quantum series does not raise new questions of safety and efficacy.

VIII. Conclusion

Based on the foregoing, the Q-switched Nd:YAG Laser Treatment Head for the Quantum series was found to be substantially equivalent to the predicate MedLite C^3 Q-switched Nd:YAG laser system (K011677), the Q-Clear laser system (K033259) and the Q-YAG 5 / Clear Light (K003460).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2005

Lumenis, Ltd.
c/o Martha Murari, Ph.D.
Senior Regulatory Affairs Associate
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K043173
Trade/Device Name: Q-switched Nd:YAG Laser Treatment Head for the Lumenis Quantum series (Quantum HR, Quantum SR and Quantum DL)
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: November 15, 2004
Received: November 16, 2004

Dear Dr. Murari:

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 (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/industry/support/index.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

Indications for Use

510(k) Number (if known): K043173

Device Name: Q-switched Nd:YAG Laser Treatment Head for the Lumenis Quantum series [Quantum HR, Quantum SR, and Quantum DL]

Indications for Use:

The Q-switched Nd:YAG Laser Treatment Head for the Quantum series in indicated for:

- Removal of dark tattoos
- Treatment of pigmented lesions

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)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K043173