K083253

5.0 510(K) SUMMARY

MAY 15 2009

Applicant:	LASEROPTEK.CO. LTD
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Address:	22750 Hawthorne Blvd., Suite 211 Torrance, CA 90505
Contact Person:	Phillip D. Cheon
Telephone / Fax / E-Mail:	Tel) 310.378.7545 Fax) 310.378.8186 E-mail) phillip@dpsii.com
Preparation Date:	September 16, 2008
Device Trade Name:	Lotus II Pulsed Er:YAG Laser System
Common Name:	Er:YAG Pulsed Surgical Laser
Classification Name:	Instrument, Surgical, Powered laser, 79-GEX, 21 CFR 878-4810

Legally Marketed Predicate Devices:

- ***DermaStar Er:YAG Laser System*** (K014057) by Asclepion-Meditec AG
- ***MCL 30 Dermablate Er:YAG Laser System*** (K042968) by Cynosure, Inc.

Description of the Lotus II Pulsed Er:YAG Laser System:

The Lotus II laser system is an Erbium:YAG laser with a wavelength of 2.94 um. Laser activation is by footswitch. Three basic elements of operations are as follows:

1) A Er:YAG crystal is used as a gain medium which produces a laser beam.
2) A resonator then amplifies the beam.
3) A lamp that contains Xe gas is used, as a pumping light source. The lamp requires a high-pressure power source device for operation. When the electric energy generated from the high-pressure power source is induced into the electrode of the lamp, it converts into light energy. This converted light energy pumps the Er:YAG crystal – a gain medium – and the light exhausted from the crystal is amplified into a specific wavelength light. As it passes between the resonant gases, laser beam radiates to an output unit.

The regulation of laser output and repetition rate can be set by the user via GUI (Graphic User Interface) and controlled by microprocessor, which interfaces with the power supply.

Intended Use of the Lotus II Pulsed Er:YAG Laser System:

The Lotus II Pulsed Er:YAG Laser System is a pulsed erbium doped yttrium-aluminum-garnet (Er:YAG) laser. It outputs laser light with a wavelength of 2940 nm, a wavelength very efficiently absorbed by the skin. It is intended for coagulation, vaporization, ablation and/or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), and ophthalmology (skin around the eyes). This includes skin resurfacing and the treatment of wrinkles.

Performance Data:	None
Conclusion:	The spec and intended uses of the Lotus II Pulsed Er:YAG Laser System are the same or very similar to those of claimed predicate devices. Because of this, performance data were not required. The Lotus II Pulsed Er:YAG Laser System is substantially equivalent to legally marketed devices. The Lotus II Pulsed Er:YAG Laser System is another safe and effective device for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery, and ophthalmology (skin around the eyes).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Laseroptek Co., Ltd.
% DPS International
Mr. Phillip Cheon
22750 Hawthorne Boulevard, #211
Torrance, California 90505

Re: K083253
Trade/Device Name: Lotus II Pulsed Er:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical insrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 12, 2009
Received: March 17, 2009

Dear Mr. Cheon:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083253

Device Name: Lotus II Pulsed Er:YAG Laser System

Indications For Use:

The Lotus II Er:YAG Laser System is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K083253