MAY 13 2008

510(K) SUMMARY

LITEDUO Dental Laser System

510(k) Number K073411

Applicant's Name: Light instruments Ltd
Tavor Building 1
Yokneam Ind. Zone
P.O.Box 223
Yokneam Elite 20692
Tel: (972)4-959-7531
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Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***LITEDUO Dental Laser*** System

Classification: **Name**: Laser Instrument, Surgical, Powered
Product Code: GEX
Regulation No: 21 CFR 878.4810
Class: II
Panel: General & Plastic Surgery

Device Description:

The LITEDUO Dental Laser is an advanced microprocessor-controlled laser system, composed of the following units:

- The control panel;
- The Er:YAG and Diode laser applicators;
- High-voltage power supply, capacitor bank and switching module;
- Diode driver and Diode laser array;
- The cooling system;
- An Er:YAG laser energy verification module.

Intended Use Statement:

The ***LiteDuo Dental Laser System*** **is intended to** aid during dental procedures performed in oral and maxillofacial surgery and dentistry.

The ***LiteDuo Dental Laser System*** is indicated for a variety of hard tissue (tooth and bone) applications, and for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry. In addition, the system is intended for light activation of bleaching materials for teeth whitening. This includes the following:

Er:YAG Laser:

Hard Tissue Indications of Erbium Laser Energy:
Caries removal, Cavity preparation, Enamel etching, Enameloplasty, excavation of pits and fissures for placement of sealant.
Bone Indications of Erbium Laser Energy:
Contact and non-contact cutting, shaving, contouring, and resection of oral osseous tissue (bone), Apicoectomy - amputation of the root end, Cutting bone to prepare a window access to the apex (apices) of the root(s), Osseoplasty, Osteotomy, Osseous crown lengthening
Soft Tissue and Periodontal Indications of Erbium Laser Energy:
Excisional and incisional biopsies, Exposure of unerupted teeth, Incision and drainage of abscesses, Gingival incision and excision, Gingivoplasties, Gingivectomies, Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias, Gingival troughing for crown impressions, Hemostasis, Implant recovery, Frenectomies and frenotomies, Fibromatosis (fibroma removal), Benign and malignant lesion removal, Operculectomy, Oral papillectomies, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Preprosthetic surgery: flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papillomas, fibromatoses benign growths, Vestibuloplasty, Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
Endodontal Indications of Erbium Laser Energy:
Tooth preparation to obtain access to root canal, Pulpotomy, Pulpotomy as an adjunct to root canal therapy, Pulp extirpation, Root canal debridement and cleaning, Root canal preparation including enlargement.

Diode Laser:

Marginal and interdental gingiva and epithelial lining of free gingiva, frenectomy frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gigngivioplasty, gingival troughing crown lengthening,

hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incision and draining of abscesses, tissue retraction, for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, removal of hyperplastic tissues, treatment of aphtous ulcers, leukoplakia, sulcular debridement (removal of diseased or inflamed soft tissue, in the periodontal pocket), pulpotomy, pulpotomy as adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of approval
LITETOUCH	K061966	27 Sep, 2006
SIROLaser	K053161	18 Jan, 2006
Opus 10	K011769	30 Aug, 2001
Vectra Laser	K060114	7 Apr. 2006

Performance Standards

LITEDUO Dental Laser System complies with U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.

- In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:
- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***EN 60825-1*** (Safety of laser products);
- ***EN 60601-2-22*** (Medical device equipment, Particular Requirements for the safety and diagnostics and therapeutic laser equipment).
- ***IEC 60601-1-2*** (Electromagnetic compatibility (EMC)

A detailed description appears in **Section 14.**

Summary of Clinical performance data

The safety and efficacy of Er:YAG Laser devices with wavelength of 2.94 micron and power up to 8.4 Watts, and Diode Laser devices with wavelength of 0.98 micron and power up to 7 Watts are well established

in scientific research and literature including procedures performed in hard and soft oral tissue, Cosmetic Endodontology and Periodontology.

Due to the comprehensive animal and clinical study performed in scientific research and published in literature, and since the power, wavelength, pulse duration and frequency of the ***LITEDUO Dental Laser*** System are well within the previous cleared values, Light Instruments believes that animal and clinical studies are not required to determine the safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Light Instruments Limited
% Mr. Yoram Levy
Light Instrument QA/RA Consultant
Tavor Building 1
Yokneam Ind. Zone
P.O. Box 223
Yokneam Elite, Israel 20692

Re: K073411
Trade/Device Name: LITEDUO Dental 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: April 10, 2008
Received: May 05, 2008

Dear Mr. Levy:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

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Indications for Use:

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Mark Rogal for mkm

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

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periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

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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) Mark R.P. Ogden for MKm
Division of General, Restorative and Neurological Devices
510(k) Number K073411