NOV - 3 2011

Section 3 510(k) Summary or Statement

510(K) Summary

This is 510(K) summary in accordance with CFR807.82(c).

A. Submitter Information:

Submitter: LightMed Corporation

Address: NO.1-1,Lane1, Pao-An St. Sec. 3,
Shulin Dist., New Taipei City 23861, Taiwan

Owner/ Operation Number: Mr. Gary Lee, President / 9040850

Contact person: Jocelyn Liu, Regulatory Affair

TEL: +886-2-2688-1726

FAX: +886-2-2676-4920

B. Device Name

Product Name: LightLas Multi-Wavelength Medical Laser System

Trade Name: LightLas 532/670

Common Name: Ophthalmic Laser, Surgical Laser

Classification Name:

86 HQF, Laser, Ophthalmic

79 GEX, Laser Power Surgical Instrument

Regulation Name:

21 CFR 886.4390, Ophthalmic Laser

21 CFR 878-4810, Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Performance standards: 21 CFR 1040.10 & 1040.11

C. Predicate Device Names:

(1) Ellex Integre Duo (K052777)

(2) Lumenis Nevus@ Varia'M Ophthalmic Laser and Delivery Devices (K022181)

(3) Nidek Multi Color Laser Photocoagulator Model MC-300 (K042785)

(4) LightMed Lightlas532 (K091534)

D. Device Description

The LightLas 532/670 system consists of a Laser Console where the Multi-Wavelength Laser is housed along with the Electronic Control system and Power Supplies and

various Laser Delivery Units (LDU's). The LDU's include:

- Slitlamp Integrated into CSO model SL980.
- Slitlamp Attachment for CSO model SL990 and other Haag Streit clones.
- Slitlamp Attachment for Zeiss model SL30 Slitlamp
- Laser Indirect Ophthalmoscope (LIO) using a Heine Omega 180 BIO.
- Endophotocoagulation handpieces (Endoprobes)

E. Intended Use

The LightLas 532 is an Ophthalmic Laser intended to coagulate or burn structures within the patient's eye and is suitable for performing the following clinical procedures:
532nm Laser:

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation
- Macular photocoagulation to treat leaking vessels
- Laser Trabeculoplasty

670nm Laser:

- Retinal/Pan Retinal Photocoagulation

The intended use has not changed from the predicate devices.

F. Technological Characteristics summary & Substantial Equivalence

The LightMed Multi-wavelength Medical Laser system of ophthalmic lasers, LightLas 532/670, has the same intended use, general design and fundamental scientific technology as the predicate devices (K052777, K022181, K042785, and K091534). Also the operating controls and functions are equivalent to these products. They have the same functional elements such as treatment wavelengths, treatment power, spot size and cooling system. Control systems such as the door interlock, and the safety systems and displays are constantly monitored in these systems for user intervention during a procedure or maintenance. There are no new hazards introduced by the Laser System as compared with the predicate devices. Therefore the Clinical effectiveness of the LightLas 532/670 is equivalent to the previously marketed products as these specifications are the key factors that will affect the treatment modality.

G. Performance Data Summary:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the LightLas 532/670 Multi-Wavelength Medical Laser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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LightMed Corporation
% Ms. Jocelyn Liu
Regulatory Affair
No. 1-1, Lane 1, Pao-An St. Sec. 3,
Shulin Dist., New Taipei City 23861
Taiwan

Re: K103547
Trade/Device Name: LightLas Multi-Wavelength Medical Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: September 28, 2011
Received: October 05, 2011

Dear Ms. Liu:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K103547

Product Name: LightLas Multi-Wavelength Medical Laser System
Trade Name: LightLas 532/670

Indications for Use:
Ophthalmology:
532nm Laser

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation
- Macular photocoagulation to treat leaking vessels
- Laser Trabeculoplasty

670nm Laser

- Retinal/Pan Retinal Photocoagulation

The intended use has not changed from the predicate devices (K052777, K022181, K042785, and K091534)

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

Concurrence of CDR, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103547