510(K) Summary SEP 1 8 2009

K091534

This is a 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 City, Taipei Hsien 23861, Taiwan

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

Contact person: Anita Chen, Regulatory Affair

TEL: +886-2-2688-1726

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B. Device Name:

Product Name: Medical Frequency Doubled YAG Laser

Trade Name: LightLas 532

Common name: Ophthalmic Laser, Surgical Laser

Classification name:

86 HQF, Laser, Ophthalmic

79 GEX, Laser Powered Surgical Instrument

Regulation Number:

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) Device Names: Novus Spectra Laser System (K022327)

(2) Device Names: Viridis Derma(K020071)

(3) Device Nambe: VariLite Laser System (K041930)

D. Device Description:

The Medical Frequency Doubled YAG Laser is a solid state, frequency-doubled, green Nd: YAG surgical laser. It's an instrument used in the photothermolysis (photocoagulation) of soft tissue at en emission wavelength of 532nm.

LightLas LaserLink : Laser delivery adapter that may be coupled to each of the above Selecta models and connected to a currently cleared LightLas 532 retinal photocoagulator to allow use of the slit lamp to deliver 532 nm continuous wave laser energy for retinal photocoagulation.

Compatible delivery devices include: slit lamps, slit lamp adapters/ attachments, laser indirect ophthalmoscopes(LIO) and endoprobe.

The intended use has not changed from the predicate devices.

E. Intended Use:

The Medical Frequency Doubled YAG Laser is intended for use in otolaryngological, dermatological and ophthalmic surgical procedures. A complete list is contained in the Indications for Use Statement.

The intended use has not changed from the predicate devices.

F. Technological Characteristics summary & Substantial Equivalence

The Medical Frequency Doubled YAG Laser has the same indications for use as the Irides-OcuLight TX (K062369). They have similar functional elements such as treatment wavelengths, pulse rates, 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.

G. Performance Data Summary:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the Medical Frequency Doubled YAG Laser System.

H. Conclusion

The LightLas 532 is substantially equivalent to predicate devices currently legally marketed for the indication of retinal photocoagulation. laser trabeculoplasty. the treatment of vascular and pigmented skin lesions, and other laser treatments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Lightmed Corporation
% Ms. Anita Chen
Regulatory Affairs
NO. 1-1, Lane 1, Pao-An St. Sec. 3
Shulin City, Tapei Hsien 23861
Taiwan

Re: K091534
Trade/Device Name: Medical Frequency Doubled YAG Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 24, 2009
Received: August 26, 2009

Dear Ms. Chen:

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 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if Known): ~~K010372~~ K091534

Product Name: Medical Frequency Doubled YAG Laser
Trade Name: LightLas 532

Indications for Use:
Ophthalmology:

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation
- Macular Treatments
- Laser Trabeculoplasty

Otolaryngology:

- Stapedectomy
- Stapedotomy
- Myringotomy
- Lysis of adhesions
- Control of bleeding
- Removal of acoustic neuromas
- Soft tissue adhesion in micro/macro otologic procedures.

Dermatology:

- Vascular lesion
- Pigmented lesion

The intended use has not changed from the predicate devices (K022327, K020071, K062369)

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

Concurrence of CDR, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

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

510(k) Number K091534