DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 15, 2016

Lightmed Corporation
% Ms. Mollie Li
Regulatory Affairs Administrator
No. 1-1, Lane 1, Pao-An St., Sec 3, Shulin Dist
New Taipei City, 23861 TW

Re: K152688
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
Dated: May 16, 2016
Received: May 18, 2016

Dear Ms. Li:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152688

Device Name
Lightlas 532/810

Indications for Use *(Describe)*
LightLas 532/810 Multi-Wavelength Medical Laser System is intended to be used for:
• Pan-retinal photocoagulation for proliferative diabetic retinopathy- with Slitlamp or Endoprobe
• Laser retinopexy for retinal tear and detachments - with Slitlamp or Endoprobe
• Focal or grid photocoagulation for clinically significant macular edema (CSME)- with Slitlamp
• Focal photocoagulation for choroidal neovascularization (CNV) including but not limited to CNV in the setting of wet age-related macular degeneration (wet AMD)- with Slitlamp
• Trabeculoplasty for primary open angle glaucoma (POAG)- with Slitlamp

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This is 510(K) summery in accordance with 21 CFR 807.92.

I. SUBMITTER

LightMed Corporation
No1-1, Ln1, Sec. 3, Pao An St., Shulin Dist., New Taipei City 23861, Taiwan, R.O.C.
TEL: +886 2 2688 1726
FAX: +886 2 2676 4920
Establishment registration number: 3008156177
Contact person: Mollie Li, Regulatory Affairs Coordinator
Daniel Shih, Regulatory Compliance Engineer
Anderson Lin/ Business Development Administrator
(USA office phone no: (949) 218-9555 Ext. 103)
Summary Preparation Date: May 16th 2016

II. DEVICE

Trade name: LightLas 532/810
The common name of the device: Laser Instrument, surgical, powered & Laser, ophthalmic
The classification name: 21 CFR 886.4390, Class II
Product code: HQF
Performance Standards: 21 CFR 1040.10 & 21 CFR 1040.11

III. PREDICATE DEVICE

Quantel Medical Supra Twin (K081946)
LightMed Corporation LightLas 532/670 (K103547)
The predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

LightLas 532/810 Multi-Wavelength Medical Laser System can emit 532 nm wavelength laser beam and 810 nm wavelength laser beam. The 532 nm wavelength source can be delivered through both output ports (Ports 1 and 2) of the laser console, while the 810 nm wavelength source is delivered through Port 1 only. Users may choose either wavelength from a LCD touch screen, and only one output port and one wavelength may be selected for use at a time. Laser wavelength selection of the system is indicated on the panel and controlled by system software.

LightLas 532/810 Multi-Wavelength Medical Laser System is intended for use by ophthalmologists for treatment of ocular pathology, and the system consists of the following functional components:

- LCD touch panel
- Laser Console
- Ophthalmic Instrument table
- CSO Slitlamp SL980 (K992836)
- Endolaser probe (K133019)

V. INDICATIONS FOR USE

LightLas 532/810 Multi-Wavelength Medical Laser System is intended to be used for:

- Pan-retinal photocoagulation for proliferative diabetic retinopathy – with Slitlamp or Endoprobe
- Laser retinopexy for retinal tear and detachments – with Slitlamp or Endoprobe
- Focal or grid photocoagulation for clinically significant macular edema (CSME) – with Slitlamp
- Focal photocoagulation for choroidal neovascularization (CNV) including but not limited to CNV in the setting of wet age-related macular degeneration (wet AMD) – with Slitlamp
- Trabeculoplasty for primary open angle glaucoma (POAG) – with Slitlamp

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Model Name	LightLas532/810	Supra Twin (Primary predicate device)	LightLas 532/670
Manufacturer	LightMed Corporation	Quantel Medical	LightMed Corporation
510K Number		K081946	K103547
Treatment Laser			
Wavelength	532 nm (Green) 810 nm (Infrared)	532 nm (Green) 810 nm (Infrared)	532 nm (Green) 670 nm (Red)
Laser type	532 nm: Diode-pumped Frequency Doubled Nd:YAG Laser 810 nm: Diode Laser	532 nm: Diode-pumped Frequency Doubled Nd:YAG Laser 810 nm: Diode Laser	532 nm: Diode-pumped Frequency Doubled Nd:YAG Laser 670 nm: Diode Laser
Power Output	532 nm: 50mW ~ 2000mW 810 nm: 50mW ~ 3000mW	532 nm: 30mW ~ 3000mW 810 nm: 30mW ~ 3000mW	532 nm: 50mW ~ 2000mW 670 nm: 50mW ~ 700mW
Laser Safety Class	4/IV	4/IV	4/IV
Exposure Time	0.01s to continuous	0.01s to continuous	0.01s to continuous
Cooling Method	Solid State Cooling with thermoelectric (Peltier) heat pump	Solid State Cooling with thermoelectric (Peltier) heat pump	Solid State Cooling with thermoelectric (Peltier) heat pump
Aiming Beam			
Type	Red Laser Diode	Red Laser Diode	Red Laser Diode
Wavelength	635-650nm (Red)	635-650nm (Red)	635-650nm (Red)
Laser power	Maximum of 1.0mW	Maximum of 1.0mW	Maximum of 1.0mW
Laser Safety Class	2/II	2/II	2/II
Others			
Power requirements: Voltage	100 to 230 Vac	100 to 240 Vac	100 to 230 Vac

The Indications for Use statement for LightLas532/810 is not identical to the

predicate devices; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The performance data to account for the differences listed in the table are provided in Section VII of this summary below.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench Testing were completed including the Finished Product final assembly quality Inspection, System Adjustment, Calibration and Testing for Laser console of LightLas 532/810 Laser System.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LightLas 532/810 device, consisting of the laser console and TruScan module integrated Slitlamp. The system complies with the IEC 60601-1, IEC 60601-2-22 and IEC 60825-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that LightLas 532/810 Laser System should perform as intended in the specified use conditions. The clinical evaluation data demonstrate that LightLas 532/810 Laser System performs comparably to the predicate devices which are currently marketed for the same intended use.