May 24, 2019

Light-Med (USA), INC.
Hedy Chiang
Regulatory Affairs Administrator
1130 Calle Cordillera
San Clemente, CA 92673

Re: K190448
Trade/Device Name: LightLas Pattern Scanning System - TruScan Pro
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: February 1, 2019
Received: February 25, 2019

Dear Hedy Chiang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190448

Device Name
TruScan Pro

Indications for Use *(Describe)*
There are four selected wavelengths (532nm, 577nm, 670nm, 810nm) in TruScan Pro Laser Console integrated with single/multi spots of TruScan module integrated with slitlamp or single spot of LIO or endo ocular probes.

The 532nm and 810nm laser wavelengths are 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

The 577nm laser wavelength is in the treatment of ocular pathology in the posterior segment; Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for
vascular and structure abnormalities of the retina and choroid including:
- Proliferative and Severe and very severe nonproliferative diabetic retinopathy
- Clinically Significant Macular edema
- Choroidal neovascularization
- Branch and central retinal vein occlusion
- The treatment of choroidal neovascularization associated with wet age-related macular degeneration
- Lattice degeneration
- Retinal tears and detachments

The 670 nm laser wavelength is indicated for retinal and pan-retinal photocoagulation.

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.

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510(k) Summary

I. SUBMITTER

LIGHTMED USA, INC.
1130 Calle Cordillera, San Clemente, CA 92673, U.S.A.
T: +1-949-218-9555
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Contact Person: Hedy Chiang/Regulatory Affairs Coordinator
Date Prepared: Apr. 26. 2019

II. DEVICE

Trade/Device Name: TruScan Pro
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF

III. PREDICATE DEVICE

Substantial equivalence to the following predicate device is as follows:

Main Predicated Device	LIGHTMED Corp. TruScan 577	K142172	Decision Date: 02/27/2015
Reference Device	LIGHTMED Corp. LightLas 532/810	K152688	Decision Date: 06/15/2016
Reference Device	LIGHTMED Corp. LightLas 577/670	K124043	Decision Date: 9/26/2013

IV. DEVICE DESCRIPTION

There are four selected laser wavelengths in TruScan Pro Laser console consists of integrated slitlamp for single and multi-spots laser delivery or optional LIO, Endo-ocular probes laser delivery units. The 532nm or 577nm laser wavelength is the primary treatment laser or configured with 670nm or 810nm secondary treatment laser to be used. Laser console is developed along with the Electronic Control system, Power Supplies, and PC Interface platform inside, and connect with 15" LCD touch display and ophthalmic Electrical Table for use.

The TruScan Pro compatible Laser delivery units include:

TruScan module Integrated CSO SL980/SL9800 slitlamp (K992836)

Laser Indirect Ophthalmoscope using a Keeler All pupil II (K854244)

Endophotocoagulation handpieces (compatible with 510(k) cleared ophthalmic endo probes)

V. INDICATIONS FOR USE

There are four selected wavelengths (532nm, 577nm, 670nm, 810nm) in TruScan Pro Laser Console integrated with single/multi spots of TruScan module integrated with slitlamp or single spot of LIO or endo-ocular probes.

The **532nm** and **810nm** laser wavelengths are 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

The **577nm** laser wavelength is in the treatment of ocular pathology in the posterior segment; retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structure abnormalities of the retina and choroid including:

- Proliferative and severe and very severe non-proliferative diabetic retinopathy

- Clinically significant macular edema
- Choroidal neovascularization
- Branch and central retinal vein occlusion
- The treatment of choroidal neovascularization associated with wet age-related macular degeneration
- Lattice degeneration
- Retinal tears and detachments

The **670nm** laser wavelength is indicated for retinal and pan-retinal photocoagulation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary of TruScan Pro design characteristics that are identical as and differ from the predicate is provided below:

Device	Subject Device	Main predicated device	Reference Device	Reference Device	Comparison of Same or Difference
Model name	TruScan Pro	TruScan 577	LightLas532/810	LightLas577/670	
Company Name	LIGHT-MED(USA), INC.	LIGHTMED Corp.	LIGHTMED Corp.	LIGHTMED Corp.	
510(k) Number	K190448	K142172	K152688	K124043	
Laser wavelength	Treatment: 532nm, 577nm, 670nm, 810nm Aiming: 635nm	Treatment: 577nm Aiming: 635nm	Treatment: 532nm, 810nm Aiming: 635nm	Treatment: 577nm, 670nm Aiming: 635nm	Same
Power Output	532nm: 2000mW 577nm: 2000mW 670nm: 700mW 810nm: 3000mW 635nm: <1mW	577: 2000mW 635nm: <1mW	532nm: 2000mW 810nm: 3000mW 635nm: <1mW	577nm: 2000mW 670nm: 700mW 635nm: <1mW	Same
Laser Safety Classification	Treatment Laser: 4/IV Aiming Laser: 2/II	Treatment Laser: 4/IV Aiming Laser: 2/II	Treatment Laser: 4/IV Aiming Laser: 2/II	Treatment Laser: 4/IV Aiming Laser: 2/II	Same
Intended use	Ophthalmic Surgical Laser System	Ophthalmic Surgical Laser System	Ophthalmic Surgical Laser System	Ophthalmic Surgical Laser System	Same
Laser Delivery Unit	Galvanometer Integrated Slitlamp LIO Endo probe	Galvanometer Integrated Slitlamp LIO Endo probe	Integrated Slitlamp LIO Endo probe	Integrated Slitlamp LIO Endo probe	
Spot size	Single spot: 50μm, 100μm, 200μm, 300μm, 400μm, 500μm, 600μm, 800μm, 1000μm Multi spots: 100μm, 200μm, 300μm, 400μm	Single spot: 50μm, 100μm, 200μm, 300μm, 400μm, 500μm, 600μm, 800μm, 1000μm Multi spots: 100μm, 200μm, 300μm, 400μm	Single spot: 50μm, 100μm, 200μm, 300μm, 400μm, 500μm, 600μm, 800μm, 1000μm	Single spot: 50μm, 100μm, 200μm, 300μm, 400μm, 500μm, 600μm, 800μm, 1000μm	Same
Exposure time	Single Spot 0.01s to 3S continuous Multi Spots 0.01s & 0.02s	Single Spot 0.01s to 3S continuous Multi Spots 0.01s & 0.02s	0.01s to 3S continuous	0.01s to 3S continuous	Same
Pattern Type	532nm: single spot, Straight Line, Square, Triangle, Circle, Arc 577nm: single spot, Straight Line, Square, Triangle, Circle, Arc 670nm: single spot 810nm: single spot	577nm: single spot, Straight Line, Square, Triangle, Circle, Arc	532nm: single spot 810nm: single spot	577nm: single spot 670nm: single spot	Same

Type of scanning system	Galvanometer	Galvanometer	NA	NA	Same as Main predicated device
Power requirements Voltage	100 to 230Vac	100 to 230Vac	100 to 230Vac	100 to 230Vac	Same
Dimensions	40.5cm L x 40.5cm W x 13 cm H	33cm L x 37cm W x 13cm H	33cm L x 37cm W x 13cm H	33cm L x 37cm W x 13cm H	Different
Weight	22Kg	33Kg	33Kg	33Kg	Different
Computer Control	YES the PC interface board is attached inside the laser console and connect with 15" touch display	YES the PC is attached with 11" LCD touch panel	YES the PC is attached with 11" LCD touch panel	YES the PC is attached with 11" LCD touch panel	Different
Cooling method	Fan cooled and TEC's for Laser Diodes and Crystal	Fan cooled and TEC's for Laser Diodes and Crystal	Fan cooled and TEC's for Laser Diodes and Crystal	Fan cooled and TEC's for Laser Diodes and Crystal	Same
Applicable Standards	ANSI AAMI60601-1 EMC IEC60825-1 IEC60601-2-22 ISO15004-1	IEC60601-1 EMC IEC60825-1 IEC60601-2-22 ISO15004-1	IEC60601-1 EMC IEC60825-1 IEC60601-2-22 ISO15004-1	IEC60601-1 EMC IEC60825-1 IEC60601-2-22 ISO15004-1	Same

TruScan Pro is an extended model to compare the main predicated device and reference devices designed and manufactured by LIGHTMED.

The indications for Use statement and Laser delivery unit for the TruScan Pro is similar with predicated devices.

The major difference between TruScan Pro and predicated devices is the hardware development in order to drive maximum four wavelengths in one laser console; however, the difference 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 prove the safety and performance of TruScan Pro are provides in Section VII of this summary below.

VII. PERFORMANCE DATA

The following performance data were provided to support substantial equivalence determination.

Biocompatibility testing

There are no direct patient contact components in TruScan Pro Laser System but the integrated slitlamp supplied by original manufacturer with patient contact component

such as chinrest and headrest were subjected to In vitro Cytotoxity, Irritation, and skin sensitization testing in accordance with FDA guidance - *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*

The patient contact materials for Chinrest and headrest are surface contact/skin device only. Contact duration is limited to less than 30 minutes. (which is shorten than 24 hours mentioned in ISO 10993 A-limited.) The Biocompatibility testing results showed patient contact materials of integrated slitlamp conform to ISO 10993-1, 10993-5, ISO 10993-10, and ISO 10993-12 standards.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on TruScan Pro, according to applicable federal and international safety and performance standards:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012
- IEC 60825-1: 2014
- IEC 60601-2-22:2007+A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- EN ISO 14971:2012
- ISO15004-1:2006

The testing results demonstrate that TruScan Pro comply with all the required standards.

Software verification and validation testing

According to the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)", the level of concern of TruScan Pro and its software is determined to be **Major**. The Software of TruScan Pro controls the delivery of laser energy. A failure of operation or latent flaw of TruScan Pro could directly result in serious injury to the patient or operator.

The software verification and validation results confirm the fulfillment of software requirement specifications.

VII. CONCLUSIONS

The TruScan Pro is substantially equivalent to the predicate devices in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The TruScan Pro is designed to comply with applicable federal and international safety and performance standards. There are no new safety and effectiveness issues being raised.