June 9, 2022

Luminance Medical Ventures, Inc.
℅ Laura Nygard
RAQA Consultant
leanRAQA, LLC
131 E Loch Lomond Dr
Oro Valley, Arizona 85737

Re: K220729
Trade/Device Name: The Luminance RED Acne Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: March 11, 2022
Received: March 14, 2022

Dear Laura Nygard:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220729

Device Name
The Luminance RED Acne Device

Indications for Use *(Describe)*
The Luminance RED Acne Device is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne.

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.

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

SECTION 5 : 510(k) Summary

5.1 Applicant/Submitter

Company Name	:	Luminance Medical Ventures, Inc.
Establishment Registration Number	:	3020491484
Phone Number	:	619-341-3848
Company Street Address	:	2310 HENDERSON AVENUE #1297
City	:	Dallas
State	:	Texas
Country	:	USA
Zip Code	:	75201

5.2 Contact Person

Full Name	:	Troy Stites
Job Title	:	Founder
Phone	:	619-341-3848
Email	:	troy@luminancemedical.com

5.3 Correspondent Information

Full Name	:	Laura Nygard
Job Title	:	RAQA Consultant
Phone	:	734-807-1282
Email	:	lauran@leanraqa.com

5.4 Date of Preparation

Date of Preparation	:	03/11/2022

5.5 Device Information

Table - 5.1 Device Information

Trade Name	The Luminance RED Acne Device
Common or Usual Name	Over-The-Counter Powered Light Based Laser For Acne
Classfication Name	21 CFR 878.4810
Regulatory Class	2
Product Code	OLP

5.6 Predicate Device(s)

Table - 5.2 Predicate Device(s)

Predicate Type	510(k) Number	Name Of Device	Name Of Manufacturer	Product Code
Primary Device	K170260	BC-001+ Acne Purifier	Oriental Inspiration Limited	OLP
Reference	K153081	Clear Bi-Light	Michael Todd, LP	OLP

5.7 Device Description

The Luminance RED Acne Device is a lightweight, handheld device that consists of a body handle and treatment head. The body handle contains 2 LEDs that emit visible blue light (415 nm +/- 10 nm) or visible red light (660 nm +/- 10 nm) through the treatment head to help reduce the appearance of mild to moderate acne. The body consists of a plastic shell which includes a button to turn the device on/off, a button for red visible light, a button for blue visible light, and a digital countdown timer. The Luminance RED Acne Device is powered by a lithium-ion battery.

5.8 Intended Use/Indications for Use

The Luminance RED Acne Device is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne.

5.9 Comparison of Technological Characteristics with Predicate

Table - 5.3 Comparison Table

Characteristics	Subject device	Predicate Device	Reference device	Substantial Equivalence Remarks
Device Name	The Luminance RED Acne Device	BC-001+ Acne Purifier	Clear Bi-Light	N/A
Applicant/Sponsor	Luminance Medical Ventures, Inc.	Oriental Inspiration Limited	Heyer Regulatory Solutions LLC	N/A
Product Code	OLP	OLP	OLP	Same
Regulation Number and Name	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	Same
510(k) Number	Not Yet Assigned	K170260	K153081	N/A
Indications for Use	Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne.	BC-001+ Acne Purifier is intended/indicated for over-the-counter use in the treatment of mild to moderate acne.	The Clear Bi-Light is indicated for the treatment of mild to moderate inflammatory acne	Same
Energy Type	LED	LED	LED	Same
OTC	Yes	Yes	Yes	Same
Wavelength	415 nm (+/-10 nm) 660nm (+/-10 nm)	415 nm ± 5 660 nm ± 5	405-420 nm 630-660 nm	Same
Dose Rate	4.5 Joules of each wavelength (red and blue) 50 mW/cm2 for each wavelength (red and blue)	50 (blue) mW/cm2 23 (red) mW/cm2	31.1 (blue) 54.6 (red)	Similar

Characteristics	Subject device	Predicate Device	Reference device	Substantial Equivalence Remarks
Treatment Regimen	Hold the fiber optic tip to the area you wish to treat. It is acceptable if the fiber optic tip is not in direct contact with the skin, but the optimal placement is on or within about 0.5 inches (1 centimeter) from the treatment area. Treat with 90 seconds of 415nm (blue light), then 90 seconds of 660nm (red light), 2 times per day, morning and night.	1.5 minutes per spot	Hold treatment face in contact with skin. Apply blue light for up to 3 minutes per skin area, followed by red light for up to 3 minutes per skin area. Can be use daily.	Similar
Treatment Area	0.20-3.1 cm^2 circle	9.1 cm^2	20 [cm2]	Similar
Power Supply	Lithium ion battery18650 Type: Lithium ion, dc Capacity: 2,200 mAh Voltage: 3.7 V Battery Type: 18650 AC charger: 100-240V at 50Hz-60Hz Rated charging voltage. 5V DC recharging current: 1.0A	Lithium-ion rechargeable battery AC charger: 100-240V at 50-60Hz, 500 mA Micro-USB socket for battery charging.	Lithium-ion rechargeable battery AC charger: 100- 240V at 50-60Hz, 500 mA	Same
Microprocessor controlled	Yes	Unknown	Yes	Same
Handheld	Yes	Yes	Yes	Same
Software	Yes, V&V per Standard IEC 62304	Yes, V&V per guidance	Yes, V&V per guidance	Similar
Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 62471:2006-07	Same
Usability Testing	Yes per Guidance and IEC 62366	Yes per Guidance	Unknown	Same

Characteristics	Subject device	Predicate Device	Reference device	Substantial Equivalence Remarks
Biocompatibility Testing	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Same

5.10 Standards and Guidances

5.10.1 Standards Applied

- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- IEC 62471 First edition 2006-07, Photobiological safety of lamps and lamp systems
- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.0 2015-01, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-57 Edition 1.0 2011-01, Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic diagnostic monitoring and cosmetic/aesthetic use
- IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

5.10.2 FDA Guidances Applied

- Use of International Standard ISO 109931 Biological evaluation of medical devices Part 1 Evaluation and testing within a risk management process Guidance for Industry and Food and Drug Administration Staff

5.11 Performance Data

5.11.1 Non Clinical

- Usability Study

5.12 Biocompatibility Testing

- Cytotoxicity
- Irritation
- Sensitization

5.13 Clinical Testing

No clinical testing was conducted as part of this 510(k) submission

5.14 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.