January 30, 2018

Luma Therapeutics
Tiffini Wittwer
Regulatory
10 Rollins Rd
Suite 120
Millbrae, California 94030

Re: K173436
Trade/Device Name: Luma Light System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: November 1, 2017
Received: November 3, 2017

Dear Tiffini Wittwer:

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.

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.

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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173436

Device Name
Luma Light System

Indications for Use *(Describe)*
The LUMA™ Light System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), sebhoreic dermatitis, and leukoderma on all skin types (I-VI).

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:

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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 displays a currently valid OMB number."*

# 2 510(k) Summary

**Table 1: 510(k) Summary**

| | |
|---|---|
| **Submitter:** | Luma Therapeutics<br>10 Rollins Rd Suite 120<br>Millbrae CA 94030 |
| **Contact Person:** | Tiffini Diage<br>Regulatory Affairs Consultant<br>Phone: 707.799.6732<br>E-mail: tdiage@raechelon.com |
| **Date Of Submission:** | November 1, 2017 |
| **Trade Name:** | Luma Light System |
| **Common Name:** | Ultraviolet Lamp for Dermatologic Disorders |
| **Classification:** | Class II, per 21 CFR 878.4630 |
| **Product Code:** | FTC |
| **Predicate Device(s):** | The subject device is equivalent to the following devices:<br>• K170489 – Skylit Phototherapy System |
| **Device Description:** | The Luma Light System is a phototherapy system intended to treat dermatological conditions such as psoriasis. The system includes a light module, an Android Nexus 4 phone, a software-based phone application (app), and a device charger. The light module contains light emitting diodes (LEDs), which create an array of narrowband UVB light centered at a wavelength between 300 - 320 nm. The light module attaches to a dressing applied to the patient's affected skin to allow for passive dosing of the lesion. This is a home use device intended to be used and operated by the patient (see technical specifications for environmental limitations). A physician will determine the dose and frequency of treatment. The app is then used by the patient to deliver treatments, provide treatment reminders and store data about prior treatments. |
| **Indication for Use:** | The LUMA™ Light System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI). |

## Substantial Equivalence Comparison:

| Characteristics | Luma Light System | Clarify Phototherapy System |
|---|---|---|
| Manufacturer | Luma Therapeutics | Skylit Phototherapy |
| 510(k) Number | TBD | K170489 |
| Classification | Class II | Class II |
| Product Code | FTC | FTC |
| Regulation | 21 CFR 878.4630 | 21 CFR 878.4630 |
| Indications for Use | The LUMA™ System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI). | The Clarify Medical Phototherapy System is an Utraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI). |
| Treatment Area | 20.2 $cm^2$ | 25.8 $cm^2$ |
| UVB Light Source | Same - LED lamps | LED lamps |
| User Interface | Touch screen on the Mobile Device | Touch screen on Mobile Device and a start button on the handheld unit |
| Max Power Output | 4.2 – 7.2 $mW/cm^2$ | 3-15 $mW/cm^2$ |
| UV light Wavelength | Same - 300 – 320 nm | 300 – 320 nm |
| Mode of operation | Same – Hand piece (light module) with wireless connection to mobile phone | Hand piece used with wireless connection to mobile phone |

| | | |
|---|---|---|
| | Physician sets frequency and duration of treatments by programming app in phone | Physician provides dosing instructions and physician can adjust time/dose based on the treatment outcome |
| Increase UVB treatment dose after each treatment | Same – Yes this capability is built into the software in accordance with the prescribed protocol | Yes, this capability is built into the SW in accordance with the prescribed protocol |
| Delivery Method | Same – Treatment window | Spot treatment window |
| Power Source | Same – Rechargeable battery | Rechargeable battery |
| Prescription stored on Device | Yes on mobile device | Yes – Cloud server |
| Use Environment | Same – Home / Physician Office | Home / Physician Office |
| IPX – Rating / water resistance | Same – not water resistant | Not water resistant |
| Communications between light module and phone | Same – Bluetooth wireless | Bluetooth wireless |
| Records retention and remote physician review of results | Treatment records stored on phone | Yes, treatment data is stored and uploaded to server for remote review |
| Timer to control treatment duration | Same – stored in the software based on prescription | Yes – stored in the software, based on Prescription |
| Software Application | Android | Android and iOS |
| Phone Provided with System | Yes | No |

**Performance Testing / Safety and Effectiveness:**

To verify that device design meets its functional and performance requirements, representative samples of the device underwent software, electrical, and mechanical testing in accordance with the following industry standards.

- IEC-60601-1 › *Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*
- EN-60601-1-2 › *Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance. Collateral Standard. Electromagnetic Compatibility. Requirements and Tests*

- IEC 60601-2-57 *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 62304: *Medical device software – Software life cycle processes*.
- Guidance for Industry and FDA Staff:
    - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued 5/11/2005),
    - Mobile Medical Applications (Issued 9/25/2013)
    - Radio Frequency Wireless Technology in Medical Devices (Issued 8/13/2013).

**Conclusion**:

The LUMA system has similar indications for use, principles of operation, and fundamental technological characteristics as compared to the predicate. Both devices are used for treating dermatological skin conditions with Ultraviolet light emitted from a LED light source. In addition, both devices have similar user interface. Any differences in product performance or features have been validated to ensure the LUMA system performs as intended and does not raise any new issues of safety and effectiveness as compared to the predicate device. Based on this information as well as documentation in support of the LUMA system, Luma Therapeutics believes the LUMA system is substantially equivalent to the predicate device.