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

May 23, 2017

Skylit Medical
Don Canal
Vice President
401 North A Street
Suite 775
San Diego, California 92101

Re: K170489
Trade/Device Name: Skylit Phototherapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: February 22, 2017
Received: February 23, 2017

Dear Don Canal:

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,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170489

Device Name
Clarify Medical Phototherapy System

Indications for Use *(Describe)*
The Clarify Medical Phototherapy System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototheraputic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and lenkoderma on all skintypes (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.

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"510(k) Summary" as required by section 807.92(c)

Date Prepared:	May 22, 2017
Manufacturer Name	Clarify Medical, Inc. 401 N. A Street, Suite 775 San Diego, CA 92101, USA Telephone: (972) 955-7644
Official Contact	Don Canal Regulatory Affairs 401 N. A Street San Diego, CA 92101, USA Telephone:(972) 955-7644 Email: don@clarifymed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Clarify Phototherapy System
Common Name	Light, Ultraviolet, Dermatological
Classification Name	Ultraviolet lamp for dermatologic disorders
Classification Regulations	21 CFR 878.4630 Class II
Product Code	FTC
Submission Type	510(k)
Classification Panel	General & Plastic Surgery
Premarket Review	ODE/DSD/General Surgery Devices Branch One (GSDB1)

Predicate Devices

The Clarify System is substantially equivalent to the other legally marketed phototherapy, UVB treatment devices. Specifically, the Clarify Phototherapy System is substantially equivalent to the Lerner Medical Inc. Levia Phototherapy System (K040062/K090097), Daavlin Distributing Co. DermaPal (K073587) and Allux, Inc. Resolve UVB Phototherapy System (K072035).

Device Description

The Clarify Phototherapy System is a handheld medical device that produces UVB light for the purpose of phototherapy. It was developed and will be marketed by Skylit Medical, Inc. DBA Clarify Medical, Inc. and is referred to herein as “Clarify Medical” or “Clarify”. The Clarify Medical Phototherapy System is an Ultraviolet Light Emitting Medical device.

It is indicated 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 system consists of the following components and accessories:

1. Handheld UV light Emission device that delivers the UVB light
2. Mobile Software Application that runs on smartphone (Android and iOS) platforms. This Application is the primary user interface, and provides patient guidance when phototherapy is delivered and treatment reminders
3. Physician Portal Software is a cloud based software application that links the patient to the prescribing physician during home therapy.

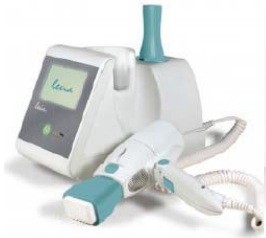
Federal (U.S.) law restricts this device to sale by or on the order of a physician.

The Clarify System delivers UV light between the wavelengths of 300 and 320 nm using Light Emitting Diodes (LEDs). The handheld device is powered by a rechargeable battery and is connected to a smartphone software application that enables the device and provides feedback during treatment. The smartphone also provides reminders on treatment days and provides a means for patient feedback and dose adjustment. The smartphone application also provides the means for the patient to take photographs for comparison purposes.

Indications for Use Statement
The system is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma on all skin types (I-VI). The device can be used in the comfort of a patient's home or in a physician's office.

Comparison to Predicate Devices
The Clarify System is substantially equivalent to the other legally marketed phototherapy, UVB treatment devices. Specifically, the Clarify Phototherapy System is substantially equivalent to the Lerner Medical Inc. Levia Phototherapy System (K040062/K090097), Daavlin Distributing Co. DermaPal (K073587) and Allux, Inc. Resolve UVB Phototherapy System (K072035). The detailed comparison between the Subject Device and the Predicate devices is provided in Table 1 below.

Table 1 – Predicate Comparison Table

	Subject Device	Predicate Device	Predicate Device	Predicate Device
	Clarify Medical Phototherapy System (Subject Device)	**Lerner Medical Devices, Inc. Levia Phototherapy System / LH-75T Phototherapy System K040062 / K090097**	**Daavlin Distributing Co. DermaPal K073587**	**Allux Resolve UVB Phototherapy System K072035**
				Image unavailable
Indications for Use	The Clarify Medical Phototherapy 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).	K040062: The Levia Phototherapy System is intended for use in UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma. The Levia Phototherapy System is intended for use on all skin types (I-VI). K090097: The LH-75T Phototherapy System is intended for use, by or under the direction of a physician, in UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis and leucoderma. The LH-75T Phototherapy System is intended for use on all skin types (I -VI).	The DermaPal® is a handheld ultraviolet light emitting fluorescent lamp. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I - VI).	The Resolve™ UVB Phototherapy System is an ultraviolet light emitting medical device for localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The Resolve™ UVB Phototherapy System is intended to be used with all Skin Types (I - VI).
Product Codes / Regulation Number	FTC / 21 CFR 878.4630	FTC / 21 CFR 878.4630	FTC / 21 CFR 878.4630	FTC / 21 CFR 878.4630
Treatment area	4.5 cm^2	3 cm^2	11.4 x 2.54 cm	12.8 x 9.0 cm

	Subject Device	Predicate Device	Predicate Device	Predicate Device
	Clarify Medical Phototherapy System (Subject Device)	**Lerner Medical Devices, Inc. Levia Phototherapy System / LH-75T Phototherapy System K040062 / K090097**	**Daavlin Distributing Co. DermaPal K073587**	**Allux Resolve UVB Phototherapy System K072035**
UVB light source	LED UV lamps	Arc Lamp	Fluorescent UV lamps	LED UV lamps
User Interface	Touch screen on Mobile Device and Start button on	Control Box with cables to handheld device	Control Box with cables to handheld device	Control Box with cables to handheld device
Max Power Output	3-15 mW/cm^2	90-100 mW/ cm^2	3.9-6.8 mW/ cm^2	1 mW/cm^2
UV light Wavelength	300-320 nm	300-320 nm	300-320 nm	300-320nm
Mode of operation	Hand piece used with wireless connection to mobile phone	Hand piece connected to console with touch screen control panel to control treatment	Hand piece used in standalone treatment mode	Patient attached unit connected to a power supply used in standalone treatment mode
	Physician provides dosing instructions and physician can adjust time/dose based on	Physician provides dosing instructions and patient can adjust time/dose based on treatment outcome	Physician provides dosing instructions and patient can adjust time/dose based on treatment outcome	Unknown
Increase UVB treatment Dose after each treatment	Yes, this capability is built into the SW in accordance with the prescribed protocol.	Yes, this capability is built into the SW in accordance with the prescribed protocol.	Instructions are provided in the DFU. Not built into the the SW, the patient must manually calculate and enter the dose.	Unknown
Delivery method	Spot treatment window	Spot treatment attachment (LiteSpot™), Quartz fiber-optic brush attachment (LiteBrush™)	Spot treatment wand with integrated comb	Spot treatment window
Power Source	Rechargeable battery	AC outlet	AC outlet	AC outlet
Prescription stored on Device	Yes – Cloud server	Yes - USB	No	No
Scalp Attachment	No	Yes	Yes	No
Use Environment	Home / Physician's office	Home / Physician's office	Home / Physician's office	Home / Physician's office

	Subject Device	Predicate Device	Predicate Device	Predicate Device
	Clarify Medical Phototherapy System (Subject Device)	**Lerner Medical Devices, Inc. Levia Phototherapy System / LH-75T Phototherapy System K040062 / K090097**	**Daavlin Distributing Co. DermaPal K073587**	**Allux Resolve UVB Phototherapy System K072035**
IPX – Rating/water Resistance	Not water resistant	Not water resistant	Not water resistant	Not water resistant
Communications between	Bluetooth wireless	Wired connection	Wired connection	Wired connection
Records retention and remote physician review of results.	Yes. Treatment data is stored and uploaded to Server for remote review	Yes. Treatment data is stored locally on the device. no remote review of data is possible	No record retention capability	No record retention capability
Treatment day/Time reminder set by User	Yes	No	No	No
Timer to control treatment duration	Yes – stored in the Software, based on Prescription	Yes – entered by the user for each treatment	Yes – entered by the user for each treatment	Yes – entered by the user for each treatment
Target Population	Patients and clinicians	Patients and clinicians	Patients and clinicians	Patients and clinicians

Summary of Performance Data – Bench

The determination of substantial equivalence is based on an assessment of non-clinical performance data. Table 2 below contains a summary of the performance testing that was submitted, referenced, or relied on in the premarket notification submission to determine substantial equivalence and how their results support a determination of substantial equivalence.

Table 2 – Performance Test Summary

Element of Comparison	Method for Safety Assessment	Test Result Meet Design Input Specifications and Demonstrate Equivalence
UBV light Source, Max Power Output	Performance Testing	Yes

Element of Comparison	Method for Safety Assessment	Test Result Meet Design Input Specifications and Demonstrate Equivalence
Power Source	Electrical Safety Testing, Battery Performance Testing	Yes
Prescription Stored on the device	System Validation	Yes
Treatment Reminders	Software Validation	Yes
Auto Calculation of treatment adjustment	System Validation	Yes
Skin Contact Materials	Performance testing	Yes
Wireless communications between handheld and console	System Validation	Yes
Records Retention	System Validation	Yes
Remote Physician Review of the results	System Validation	Yes

Performance Test Conclusion

Based on technical comparison, the Subject device has been shown to be equivalent to the predicate devices.

Standards and Guidance Documents

Optical emissions testing:

Clarify has verified that optical emissions within the 300-320nm range is equivalent to that of the predicate devices. With the LEDs switched on, the optical emissions spectrum is measured at the treatment surface. The biologically weighted emissions curve is then computed using the International Commission on Illumination accepted erythema curve. Clarify has completed verification testing to demonstrate that the weighted peak of emissions is within the established therapeutic range (300-320nm). The optical power at the treatment surface is also measured to ensure it meets the specified requirements. The device has been evaluated for safety and performance in accordance with 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.*

Electrical safety:

Clarify has completed testing to the applicable sections of IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-4 Medical electrical equipment – Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems.

Software and wireless safety:
Due to the software component and wireless functionality of the device, Clarify will review and comply with the following FDA guidance documents: Guidance for Industry and FDA Staff: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued 5/11/2005),* Guidance for Industry and FDA Staff: *Mobile Medical Applications (Issued 9/25/2013),* and Guidance for Industry and FDA Staff: *Radio Frequency Wireless Technology in Medical Devices (Issued 8/13/2013).* The following standard has been considered when evaluating the software: IEC 62304: *Medical device software – Software life cycle processes.*

Electromagnetic compatibility (EMC):
Since the system includes electronics, EMC has been assessed according to IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances.

Biocompatibility:
The distal end of the Clarify Phototherapy System will have limited contact duration (< 24 hours) with skin and is therefore considered a "surface device" according to Annex A of ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Based on the device type and contact duration, FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"* recommends the following biocompatibility tests be performed: cytotoxicity, sensitization, and irritation. The Clarify Device distal end material has been tested to ISO-10993.

Human factors:
Clarify medical has completed numerous formative studies and software validation of the Clarify System. Clarify medical will not market the device until compliance with IEC 62366: *Medical devices – Application of usability engineering to medical devices is verified by an independent third party.*
