June 24, 2021

GlobalMed Technologies
Lisa Thorson
Director of Regulatory Affairs
163 Camino Dorado, Ste B
Napa, California 94558

Re: K210948
Trade/Device Name: Omnilux CLEAR
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 18, 2021
Received: March 30, 2021

Dear Lisa Thorson:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210948

Device Name
Omnilux CLEAR

Indications for Use *(Describe)*
The Omnilux CLEAR acne facemask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face.

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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Section 5: 510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Submitter's Name: Globalmed Technologies

Submitter's Address: 163 Camino Dorado, Ste B Napa, CA 94558

Contact Person: Lisa Thorson Director Regulatory Affairs GlobalMed Technologies 163 Camino Dorado, Ste B Napa, CA 94558

Date Prepared: June 18th 2021

Device Trade Name: Omnilux CLEAR

Device Classification Information:

Regulation Number	Device Classification name	Device Class	Product Code	Classification Panel	Type
21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	Over-The-Counter Powered Light-Based Laser For Acne	Class 2	OLP	General & Plastic Surgery	Traditional 510 (k)

5.1. Device Description

The Omnilux CLEAR consists of.

1. Silicon flexible face mask
2. Controller
3. Power supply and country specific adaptors
4. USB C to USB A connector
5. 2 x Velcro Straps

The Omnilux CLEAR acne facemask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face. The system consists of a flexible silicon mask (1) that contains light emitting diodes (LEDs) and a controller (2). The LEDs generate the light. The mask is worn on the face and is held in place by two adjustable Velcro straps (5). The mask compromises of 2 surfaces. An inner surface that contacts the skin and an outer surface. Both surfaces are constructed of medical grade silicon.

The controller (2) switches the LEDs ON/OFF and controls power to the mask. The controller contains a rechargeable Lithium-ion polymer battery. The controller uses a visible display comprising of 3 micro-LEDs to show the user the battery charge status of the device.

The power supply (3) is used to charge the Lithium battery and is connected to a suitable mains outlet via a 2 or 3 pin input socket and wall plug. The power cable is connected to the controller by a standard micro–USB A-C connector (4). The Omnilux CLEAR mask cannot be operated while charging.

The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The equipment does not require checks on the light output as the LEDs do not dim with age to any practical extent.

5.2. Intended Use

The Omnilux CLEAR acne facemask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face.

5.3. Substantial Equivalence

The Omnilux CLEAR mask is substantially equivalent to the Acne Light Therapy Wand (K160691). The Omnilux CLEAR Mask is predicated against the Acne Light Therapy Wand because both devices are LED phototherapy devices intended to emit light in the red and blue region of the light spectrum and indicated for the treatment of mild to moderate acne vulgaris.

5.3.1 Summary of Substantial Equivalence

Description	Omnilux CLEAR	K160691 Acne Light Therapy Wand	K081307 Omnilux CLEAR-U	Significant differences
Device Manufacturer	Globalmed Technologies	Zuko, Inc	Photo Therapeutics Inc.	na
Device Trade Name	Omnilux CLEAR™	Acne Light Therapy Wand	Omnilux CLEAR-U™	na
510(K) Number	-	K160691	K081307	na
Device Common Name	Omnilux CLEAR	Acne Light Therapy System	Omnilux CLEAR-U	na
Device Classification name	Over-The-Counter Powered Light-Based Laser for Acne	Over-The-Counter Powered Light-Based Laser for Acne	Light Based Over the Counter Acne Reduction	Identical
Device Product Code	OLP	OLP	OLP	Identical
Regulation Number	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	Identical

Description	Omnilux CLEAR	K160691 Acne Light Therapy Wand	K081307 Omnilux CLEAR-U	Significant differences
FDA Device Classification	Class II	Class II	Class II	Identical
Use	Over the Counter	Over the Counter	Over the Counter	Identical
Intended use and Indications	The Omnilux CLEAR acne facemask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris on the face.	The Acne Light Therapy Wand is an over-the-counter device that uses a combination of blue light and red light and is indicated to treat mild to moderate inflammatory acne	The Omnilux CLEAR-U is an over-the-counter device that is intended for the use in the treatment of mild to moderate acne vulgaris.	Identical
Intended Location of Use	Face	Face	Face	Identical
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Identical
Peak Wavelength (FWHM)	Red: 630nm +/- 5nm. Blue: 412.5nm +/- 7.5nm	Red: 633 ± 4nm Blue: 442 ± 4nm	Red: 633nm +/- 6nm Blue:415nm +/ 5nm	Equivalent
Intensity (mW/cm^2)	Blue 28 mw/cm^2 Red 16 mw/cm^2	Blue 26.5 mw/cm^2 Red 7.5 mw/cm^2	Blue 40mw/cm2 Red 70mw/cm2	Equivalent
Total Intensity (mW/cm^2)	44mw/cm^2	34mw/cm^2	110 mw/cm^2	Equivalent

Description	Omnilux CLEAR	K160691 Acne Light Therapy Wand	K081307 Omnilux CLEAR-U	Significant differences
Treatment time	10 Minutes	6 minutes[1]	20 minutes	Equivalent
Dose	Blue 16.8J/cm^2 Red 9.6J/cm^2	Blue 9.6J/cm^2 Red 2.6J/cm^2	Blue 24J/cm^2 Red 42J/cm^2	Equivalent
Treatment protocol (Treatment time)	4 x weekly, 6 weeks	Daily	2 x weekly, 4 weeks	Similar
Timers	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration	Identical
Software Controlled	Yes	Yes	Yes	Identical

1. Mathematically derived

5.3.2. Substantial Equivalency and Comparison of Technological Similarities & Differences

From the comparative table above, the Omnilux CLEAR acne facemask demonstrates equivalence to the Acne Light therapy Wand K160691. The key similarities are;

i. The intended use of the Omnilux CLEAR mask is equivalent to the listed predicates; an over-the-counter device that is intended for the use in the treatment of mild to moderate acne vulgaris.
ii. Devices are phototherapy units utilizing light emitting diodes that emit in the red and blue spectrum.
iii. The wavelength spectrum of the devices is equivalent.
iv. The devices have a similar individual and cumulative power densities and deliver a similar single and cumulative dose over the treatment protocol course.

There are therefore no significant differences between the proposed device and predicate device. Where there are differences these have been addressed by non-clinical performance testing to the following applicable standards

5.4. Non- clinical performance testing

The Omnilux CLEAR system has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

IEC/EN 60601-1: 2006 + A12:2014 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC/EN 60601-1-2: 2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests including FCC 47 CFR Part 15, Sub Part B

IEC 60601-1-11:2015 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 62471:2008. Photobiological safety of lamps and lamp systems.

IEC62133:2012 2nd ed. Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.

EN ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

EN ISO 10993-10:2010 ISO 10993-10 Third Edition 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN 62304: 2006 (ed. 1.0) Medical Device Software - Software Life Cycle Processes.

ISO 14971: 2012 Medical Devices - Application of Risk Management to Medical Devices

In addition to the aforementioned standards the Omnilux CLEAR labelling was subject to label comprehension testing. With respect to medical devices available without the intervention of a physician, termed 'Over the Counter' (OTC). To determine the effectiveness of labelling pertaining to a medical device, the labelling and device was tested with an appropriate random sample of users.

A study was conducted and is appended to this submission, demonstrating comprehension of the Omnilux CLEAR labelling. 27 subjects took part in the study, 14:13 M:F, average age 33.6 years (range 17-65). Six subjects identified English as their second language. In terms of ethnicity two subjects identified as Hispanic, one Native American, one black/African, five Asian, and three Arabic. The average number of words incorrect in the REALM reading test was 5, giving a mean reading ability of 61 (High school) (range 55-66).

No new use errors, hazards, hazardous situations, or hazard-related use scenarios were discovered during testing. Further improvement of the user interface design as it relates to safety was deemed unnecessary and there were no suggested revisions to the version of the user manual or box packaging tested.

The comprehension and use test demonstrated that the Omnilux CLEAR labelling could be used by lay persons to safely and effectively operate the device to attain its intended use and purpose.

Clinical Performance

Since the Omnilux CLEAR mask raises no new questions in terms of safety and efficacy, clinical data is not required.

Statement of Substantial Equivalence:

513(i) of the FD&C Act (21 U.S.C. 360c(i) states that for substantial equivalence a proposed device is required to have the same intended use and similar technological characteristics as the predicate device. Where there are differences in technological characteristics, these can be negated by appropriate clinical or scientific data demonstrating that the proposed device is as safe and effective as the predicate device, and that the proposed device does not raise any different questions of safety and effectiveness than the predicate device for the same intended use.

Globalmed technologies has demonstrated that the Omnilux CLEAR mask has an identical intended use, has the same generic classification and basic principles and technologies as the primary predicate device**.** Both devices utilize red and blue wavelengths of light with similar power densities and equivalent dose of light.

Globalmed Technologies has conducted non-clinical performance testing applicable to those general controls deemed necessary by the agency for this product classification and has determined that the Omnilux CLEAR raises no new questions relating to safety and therefore has demonstrated that the Omnilux CLEAR mask is substantially equivalent to the referenced predicate Acne Light therapy Wand (K160691)

June 18th 2021