

510(k) Summary for illuMask Acne Light Therapy Mask

1. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Robert Seiple, RAC. Sr. Consultant QA/RA

2. Date Prepared

12 December 2012

AUG 28 2013

Revised 27 August 2013

3. General Information

Trade/Proprietary Name: illuMask Acne Light Therapy Mask
Common/Usual Name: Acne Light Therapy System
Classification Name: Over-the-counter powered light based laser for acne¹
Classification Regulation: 21CFR 878.4810
Classification Panel: General and Plastic Surgery
Product Code: OLP
Device Class: II

4. Predicate Device

Omnilux Clear-U Acne Treatment System. Manufactured by PhotoTherapeutics, Ltd.
Montgomeryville, PA 18936. K081307.

5. Device Description

The IlluMask Acne Light Therapy device uses known LED light therapy technology for the treatment of mild to moderate acne. A combination of red light (630nm) and blue light (445nm) is emitted.

Users place the lightweight mask over the face press the On button on the controller button to start treatment. The device will automatically turn off after each treatment, and there is a total of 30 treatments.

¹ NOTE: OLP is the best description and closest match to this device. However the device uses LED light sources; there is no coherent (laser) light involved.

6. Intended Use

The illuMask Acne Light Therapy Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

7. Technological Characteristics and Substantial Equivalence

The following table compares the PhotoTherapeutics Omnilux Clear-U device (K081307) to the illuMask device with respect to intended use, technological characteristics, principles of operation and performance data.

Device Comparison Table

Trade Name	IlluMask Acne Light Therapy	Predicate Device – PhotoTherapeutics Ltd., Omnilux Clear-U (K081307)
510(k) Number	To be assigned	K081307
Product Code	OLP	OLP
Indications for Use	IlluMask Acne Light Therapy Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.	The Omnilux Clear-U is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.
Over-the- Counter Use	Yes	Yes
Energy Type (Technology)	LEDs (Light emitting diodes)	LEDs (Light emitting diodes)
Wavelength (nm)	Blue light: 445nm Red light: 630nm	Blue light: 415nm Red light: 633nm

Dose (J/cm ²)	Blue Light: 10.44 J/cm ² Red Light: 17.91 J/cm ²	Blue Light: 10.46 J/cm ² Red Light: 21.31 J/cm ²
IEC 60601 Compliant	Yes	Yes

8. Non-Clinical Testing

This device is in conformity with IEC 60601-1 3rd Edition electrical safety testing, IEC 60601-1-2 EMC testing and IEC 62471 photobiological safety testing.

Additionally, Usability and Self-Section Studies were conducted and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended.

The May 2013 Usability Study was conducted to provide a basis for the Company to gather data from the lay-person relative to level of understanding of what the device is, what the device does and how it works. This Study addressed the level of understanding of the layperson from three aspects:

1. The Outer packing and box label
2. The Instructions for Use (Manual included inside the packaging)
3. The Use of the device by laypersons

The study was conducted by an independent testing group and enrolled a total of 35 participants, male and female, from 12 – 33 years of age. Each of the participants were provided the opportunity of reviewing the illuMask product and written information about the device followed by their actual using the device. The participants were asked to complete questionnaires regarding the labeling and use of the device and were observed/evaluated by monitors to assess their understanding of the device.

The Usability Study results demonstrate that the illuMask is easy to use by the layperson. The overall success rate for the participants in all areas of using the device was greater than 85.7%. The labeling accompanying the illuMask is easy to understand and was comprehended by the majority of the participants. The overall success rate for the participants in all areas of labeling was greater than 87.2%.

The July 2013 Self Selection Study was conducted to evaluate the lay person's understanding of minor revisions to the external packaging i.e., clarification of mild, moderate and severe acne by the addition of graphics and the addition of Warnings / Precautions on the external labelling, etc. The participant demographics included a cross section of individuals representative of the US population which the illuMask is designed for. The study was conducted in a typical retail / shopping mall environment and included 47 randomly selected male and female shoppers ranging in age from 12 to 37 years.

The results of the study showed that 100% of participants found that the package labeling provided sufficient information for them to determine if the product was for them based on the presence, absence or severity of acne and that the information provided sufficient information for them to assess the warnings and risks of using the product.

9. Clinical Summary

An IRB (Institutional Review Board) approved 12-week clinical study was conducted with the illuMask Acne Light Therapy Mask to assess the safety and efficacy of the device in normal therapeutic use for the treatment of mild to moderate acne vulgaris. Note that the device was determined to be a non-significant risk (NSR) device by the governing, independent IRB based on guidance written by the FDA, titled "Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies."

Inclusion criteria for the study stated that subjects be aged 14-40 and have 10 or more acne lesions with mild to moderate acne. There were no exclusion criteria for skin type – all skin types as classified in the Fitzpatrick Classification Scale were included in the study.

A Treatment Period of 30 patients was studied and compared to a Washout Period of 30 patients. The same set of patients were followed for total of 12 weeks with the first 4 weeks being the Washout Period and the last 8 weeks being the Treatment Period. During the Washout Period, patients were given a basic facial cleanser to use in the morning and evening. None of these patients were exposed to any forms of treatment during the Washout Period; the illuMask device was not used. In the Treatment Period, subjects were only allowed to use the illuMask device and a basic facial cleaner in the morning and evening.

The principal investigator and patients recorded clinical outcomes using various matrices, including the FDA Global Acne Severity Scale, lesion counts, patient self-evaluations, standardized clinical photography, and documentation of adverse events over Baseline, Week 4, and Week 8 assessment periods. Additionally, two independent doctors conducted physician grading on the clinical photographs, which were evaluated in a blinded and randomized manner, over Baseline, Week 4, and Week 8 assessment periods.

Washout Period Results:

- In the Washout Period, 27 of the 30 subjects completed the study. The three subjects who did not complete the study were due to lack of patient follow-through for reasons outside the study; no subjects were dropped because of adverse reactions or dislike of the product.
- The Washout Period showed a 3.13% increase in total acne lesion count from the beginning to the end of the 4-week period. This difference was minor and not clinically significant. Thus, the Washout Period showed no difference in total lesion count.

Treatment Period Results:

- In the Treatment Period, 27 of the 30 subjects completed the study. The three subjects who did not complete the study were due to lack of patient follow-through for reasons outside the study; no subjects were dropped because of adverse reactions or dislike of the product.
- At the end of the 8 week Treatment Period, patients showed a 82.8% decrease in the number of inflammatory acne lesions, 71.2% decrease in the number of non-inflammatory acne lesions, and a 50% improvement in acne severity in accordance with the FDA Global Acne Severity Scale, which corresponds to a median movement of 2 points. This clinical grading, including the acne counts, was conducted in person by the principal investigator.
- Patient self-assessment for 14 attributes, including Appearance of pimples, Number of pimples, Appearance of redness associated with pimples and Size of pimples all showed continued improvement throughout the 8 week Treatment Period.
- Additionally, an average of the two independent doctor evaluations of the clinical photographs showed at week 4, subjects showed a reduction of total acne lesions by 36%; and at week 8, a reduction by 65.8%.

In summary, patients experienced much greater decreases in total lesion counts in the Treatment Period than in the Washout Period at both Weeks 4 and 8. For the Treatment Period, improvements were noted across all clinical endpoints. Patient compliance, satisfaction and questionnaire acne grading were all highly favorable. There were no serious adverse events reported by the patients and the physician investigator.

10. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the

predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

We have shown in this 510(k) submission that the Company has found no significant differences between the illuMask device and the predicate device, and that the illuMask device raises no new issues of safety and effectiveness. The illuMask Acne Light Therapy Mask, as designed and manufactured, has been found to be substantially equivalent to the referenced predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 28, 2013

La Lumiere, LLC
% Emergo Global Consulting, LLC
Robert Seiple, RAC
611 West 57th Street
Austin, Texas 78701

Re: K123999

Trade/Device Name: illuMask Acne Light Therapy Mask
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: July 26, 2013
Received: July 29, 2013

Dear Mr. Seiple:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123999

Device Name: illuMask Acne Light Therapy Mask

Indications for Use:

The illuMask Acne Light Therapy Mask is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden

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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K123999