May 1, 2018

Omm Imports, Inc. d/b/a Zero Gravity
% Ms. Susan Anthoney-Dewet
Aegis, Inc
2424 Dempster Drive
Coralville, Iowa 52241

Re: K172555
Trade/Device Name: Sapphire, Elevare Sapphire
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: April 19, 2018
Received: April 20, 2018

Dear Ms. Anthoney-Dewet:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172555

Device Name
SAPPHIRE

Indications for Use *(Describe)*
The SAPPHIRE is an over –the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use in the treatment of mild to moderate inflammatory 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

K172555

This summary of 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 807.92

Submission Date: August 23, 2017

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
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Coralville, IA 52241
Tel.: 865-982-5552
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On behalf of Sponsor: Omm Imports, Inc. d/b/a Zero Gravity
Attn: Moti Shenfarber
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2. General Information

2.1 Classification Name: Light Based Over-The-Counter Powered Light Based Laser For Acne

2.2 Common/Usual Name: Blue Light Therapy for Acne

2.3 Proprietary Names: Sapphire

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OLP

3. Predicate Device(s):

Primary Predicate Device: K121435 – Silk'n Blue (Home Skinovations LTD)

Secondary Predicate Device: K131461 – LightStim for Acne Mini (LED Intellectual Properties LLC)

4. Device Description:

The Sapphire device is an over-the-counter, battery powered, hand-held device that emits light energy in the blue spectrum for the treatment of mild to moderate inflammatory acne by emitting 50 mW/cm^2 of blue (415 nm +/- 5nm) light via an electric light emitting diode [LEDs] energy source. The Sapphire device operates by a cordless system drawing upon its rechargeable Li-Ion batteries to deliver the treatment. The unit is applied directly to the skin to ensure consistent administration of light during each treatment. There are no user settings or adjustments required. The device does not contain any user serviceable components. The device is sold as Over the Counter (OTC).

5. Indications / Intended Use:

The SAPPHIRE is an over –the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use in the treatment of mild to moderate inflammatory acne.

6. Technological Characteristics & Substantial Equivalency:

Summary of the technological characteristics of the device compared to predicate device:

Device	**Silk 'N Blue** **Home Skinovations, LTD.** **K121435** A Predicate Device	**LightStim for Acne Mini** **LED Intellectual Properties, LLC** **K131461** A Predicate Device	**Sapphire** **Zero Gravity, LLC** **K172555** This Submission
Indications	The Silkn Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne	LightStim for Acne Mini is an over-the-counter, hand held device intended for the use in the treatment of mild to moderate acne.	The SAPPHIRE is an over –the -counter hand held, battery operated, light therapy device that uses light emitting diodes (LEDs) that emit a specific wavelength of 415nm (Blue Light) that is intended for use in the treatment of mild to moderate inflammatory acne.
Handheld	Yes	Yes	Yes
Wavelength	415 nm +/- 15nm	415 nm +/- 6nm	415 nm +/- 5nm

Device	Silk 'N Blue Home Skinovations, LTD. K121435 A Predicate Device	LightStim for Acne Mini LED Intellectual Properties, LLC K131461 A Predicate Device	Sapphire Zero Gravity, LLC K172555 This Submission
Modes	On/Off	On/Off	On/Off
Energy Level	50 mW/cm2	50 mW/cm2	50 mW/cm2
Treatment Time	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)	3-4 minutes per area	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)
Total Energy delivered per Tx	12 J/cm2	9-12 J/cm2	12 J/cm2
Location for Use	OTC	OTC	OTC

1. Has the same intended use as the predicate(s) (i.e., Treatment of mild to moderate inflammatory acne ;

2. Has the same output (i.e., 50 mW/cm2 **)** as the predicate(s);

3. Utilizes the same wavelength (i.e., **415** nm +/- 5nm) as the predicate device(s);

4. Utilizes the same standard dose (i.e., **12J/cm2**) as the predicate device(s);

The Sapphire device and the above referenced predicate devices are Over the Counter devices used to treat mild to moderate inflammatory acne as defined in 21 CFR § 878.4810. These devices utilize blue diodes at 415nm to provide narrow bands of light energy to treat mild to moderate inflammatory acne vulgaris. The performance achieved by these devices is similar with equal power output. The devices are handheld, and intended to be placed directly on the skin. They are manufactured out of similar materials. Based upon comparison to the predicate device, the Sapphire device has the same intended use, with similar technological characteristics as the predicate device. The system performs as intended and does not raise any new safety or effectiveness issues.

7. Performance Data/Non-Clinical Testing:

Testing of the Sapphire device included safety testing to various international standards, bench testing--functional performance testing (power output), software validation testing and user safety testing.

The results of this testing are as follows:

Conforms to international consensus standards:

ELECTRICAL SAFETY:
Recognition Number 19-4:

- IEC60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

EMC:
Recognition Number 19-8:

- 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

BATTERY SAFETY:
Recognition Number 19-13:

- IEC 62133;2013: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

HOME HEALTHCARE ENVIRONMENT:
Recognition Number 19-14:

- IEC 60601-1-11 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 Home Healthcare Environment

LAMP SAFETY:
Recognition Number 12-249:

- IEC 62471 First Edition 2006-07, Photobiological Safety Of Lamps And Lamp Systems. (Radiology)

BIOCOMPATIBILITY:
Recognition Number 2-156:

- ISO 10993-1:2009/(R) 2013, Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process.

Recognition Number 2-153:

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

Recognition Number 2-174:

- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

The Sapphire device's software was tested and validated in accordance with FDA's *"Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."*

A Usability/Label Comprehension Study was conducted with 35 participants.
The results of the study found that:
96% of the participants were able to comprehend the labeling.
96% of the participants were able to use the device successfully.

User Safety testing reflects device can be used in a safe and effective manner.

9. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, and treatment regimes the manufacturer believes that no significant differences exist between the device and the predicate device. Therefore substantial equivalency is requested.