June 7, 2018

Omm Imports d/b/a Zero Gravity
% Susan Anthoney-Dewet
FDA Consultant
Aegis, Inc
2424 Dempster Dive
Coralville, Iowa 52241

Re: K172909
Trade/Device Name: Elevare Plus
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: OHS
Dated: August 30, 2017
Received: September 25, 2017

Dear Susan 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 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)*
K172909

Device Name
ELEVARE PLUS

Indications for Use *(Describe)*
The Elevare Plus is an Over-the-Counter (OTC) device intended for the use in treating wrinkles 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)

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)*

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."

510(k) Summary

K172909

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

Submission Date: December 15, 2016

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
2424 Dempster Drive
Coralville, IA 52241
Tel.: 865-982-5552
Email: sue@fdalistingconsultants.com

On behalf of Sponsor: Omm Imports, Inc. d/b/a Zero Gravity
9737 NW 41st Street STE 234
Doral, FL 33178

2. General Information

2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction Device

2.2 Common/Usual Name: Red/IR Light Therapy Device

2.3 Proprietary Names: Elevare Plus

2.4 Classification: Class II

2.5 Classification Number: 878.4810

2.6 Product Code: OHS

2.7 Regulation Medical Specialty: General & Plastic Surgery

2.8 Review Panel: Office of Device Evaluation (ODE)
Division of Surgical Devices (DSD)
General Surgery Devices Branch One - Light Based/Laser (GSDB1)

3. Predicate Device(s):

Predicate Device: K141181 -NUVE for Wrinkles (LED Technologies, LLC)

Reference Devices:

1. K120775 – LightStim for Wrinkles (LED Intellectual)
2. K120560- Trinity Wrinkle Remover (Carol Cole Company)

4. Device Description:

The Elevare Plus is an over-the-counter, battery powered, hand-held light emitting diode (LED) device that emits light energy in the red and I/R spectrum for the treatment of wrinkles on the face. The system components include the handheld unit containing the LED array, 2 Li-ion rechargeable batteries, power adapter, charging cord, charging cradle and travel case.

The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components. The device is sold as Over the Counter (OTC).

5. Indications / Intended Use:

The Elevare Plus is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.

6. Comparison Of Technological Characteristics With The Predicate Device:

Predicate Comparison Chart

Device	**Elevare Plus** **Omm Imports, Inc. d/b/a Zero Gravity** **K172909** This Submission	**NUVE for Wrinkles** **LED Technologies, LLC** **K141181** A Predicate Device	**LightStim for Wrinkles** **LED Intellectual** **K120775** A Reference Device	**Trinity Wrinkle Remover** **Carol Cole Company** **K120560** A Reference Device
Indications	The Elevare + is an Over-the-Counter (OTC) device intended for the use in treating wrinkles on the face.	The Nüve for Wrinkles is an Over-the-Counter (OTC) device intended for the use in treating full-face wrinkles.	The Lightstim for Wrinkles is an OTC hand-held device intended for the use in the treatment of full-face wrinkles	The Trinity Wrinkle Remover is an OTC hand-held device intended for use in the treatment of full-face wrinkles
Anatomical Sites	Entire Face	Entire Face	Entire Face	Entire Face
Handheld	Yes	Yes	Yes	Yes
Wavelengths	610, 630, 660, 850nm	605,630,660,880	605,630,660,855n	605,628,642,850n

	+/- 5nm	nm	m	m
Safety Features	Skin Contact Sensor, Fan, Temperatur e Sensor, in-activity timer	Unknown	Unknown	unknown
Irradiance source	LED	LED	LED	LED
Visible light LEDs	Yes	Yes	Yes	Yes
LED Array/Arrangeme nt	25 LEDs Over 17 cm2	60 LEDs. Over 30cm2	72 LEDs. Over 40cm2	36 LEDs. Over 1.25"D
Energy Level (mW/cm2)	65 mW total (+/- 5 mW)	65 mW total (in 510k Summary)	65 mW total (in 510k Summary)	Unknown
Power Supply	2 Li-Ion rechargeable batteries	28v DC power supply	9-volt DC power transformer	4 rechargeable batteries
Treatment Time	3 minutes daily, 5 days per week for 8 weeks	3 minutes daily, 5 days per week for 8 weeks	3 minutes daily, 5 days per week for 8 weeks	3 minutes each area, 21 minutes total minimum 5 days per week for 8 weeks
Target Population	Individuals with wrinkles on the face	Individuals with wrinkles on the face	Individuals with wrinkles on the face	Individuals with wrinkles on the face
Location for Use	OTC	OTC	OTC	OTC

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

The Elevare Plus has the same indications for use, treatment time, and treatment regime as the predicate device. The proposed device uses a different infrared wavelength than the predicate device, however the sponsor's use of the 850nm is identical to the reference devices K120775 (LightStim for Wrinkles) and within +/- 5nm to the reference device K120560- (Trinity Wrinkle Remover). The sponsor is certain that the difference in number of LEDs, treatment surface area, and slightly different power output does not affect the safety or efficacy of the device as there are a wide range of number of LEDs and power output devices cleared under device code OHS. Scientific and Performance Data i.e. bench

testing and safety testing included in this submission shows the Elevare Plus device is substantially equivalent to the predicate and reference devices. Based on technology, similar design, wavelength parameters and treatment regime these differences between the Elevare Plus device and predicate device does not adversely affect the safety or efficacy of the device

7. Performance Data/Non-Clinical Testing:

The conclusions drawn from the nonclinical testing below demonstrate that the Elevare Plus device is substantially equivalent to the legally marketed devices identified in section 3.

SAFETY TESTING

The Elevare Plus device has been tested and conforms to international consensus standards:

ELECTRICAL SAFETY:

Recognition Number 19-4:

- IEC/EN 60601-1:2005 Edition 3/(R)2012 And A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))

EMC:

Recognition Number 19-8:

- IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances- Requirements And Tests. (General II (ES/EMC))

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. (Biocompatibility)

Recognition Number 2-153:

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

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. (Biocompatibility)

ADDITIONAL SAFETY TESTING:

Recognition Number 12-249:

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

Recognition Number 19-14:

- IEC 60601-1-11 Edition 2.0 2015-01, 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

The Elevare Plus device has been tested to ensure the device meets specifications:

PERFORMANCE TESTING:

- **Software Validation Testing**
  The Elevare Plus 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."*

- **Skin Temperature Testing**
  Two devices were tested for heat output, with the treatment surface contacting the skin. Temperatures were recorded every 1 minute, up to 30 minutes, using a calibrated digital temperature sensor, around areas of the face. The test was performed under nominal use conditions and the device used in accordance with the recommended use approach (continuous movement during treatment). The test results concluded that the Elevare Plus device was within specification of 41+/- 2 ^{o}C and did not elevate skin temperature above 43^{o}C.

- **Wavelength/Power Output Testing**
  The Elevare Plus device was tested for the following optical and electrical characteristics to ensure product meets specifications:

    1. Radiant Flux (Output energy), W
    2. Output energy Spectral distribution, W/nm

PREDICATE COMPARISON TESTING:

Evaluation testing was done on several FDA cleared devices that have the same indications for use i.e. treating wrinkles on the face.
The devices were evaluated for total power output and specific irradiance levels (Spectral Flux was measured) for each of the stated wavelengths cited in the respective device's 510k Summary.

The conclusion from this testing demonstrated that the Elevare Plus device is substantially equivalent to other legally marketed devices.

8. Substantial Equivalence Conclusion

After an analysis of the safety, indications, intended uses, performance, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer believes that no significant differences exist between the device and the predicate and reference devices and no new issues arise for safety and effectiveness. Therefore substantial equivalency is hereby requested.