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

March 24, 2017

VITAGE LED Ltd.
% Sue D'Arcy
Consultant
iSmart Marketing Services
129 Green Lanes, Wylde Green
Sutton Coldfield, B735LT GB

Re: K162556
Trade/Device Name: LIGHTFUSION LED System
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: GEX
Dated: February 23, 2017
Received: February 23, 2017

Dear Sue D'Arcy:

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)*
K162556

Device Name
LIGHTFUSION LED System

Indications for Use *(Describe)*
The proposed intended use of the Lightfusion™ LED system is to emit energy in the RED and Near Infra-Red (NIR) regions of the spectrum and is indicated for the treatment of periorbital wrinkles.

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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VITAGE LED System
Traditional 510(k)

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: VITAGE LED Ltd

Submitter's Address: VITAGE LED Limited, The Pavilion, Josselin Road, Basildon, Essex. SS13 1QB

Phone: +44 (0) 333 014 2434

User Fee Organisation Number: MD6090255

Contact Person: Susan D'Arcy iSMART Marketing Services, 129 Green Lanes, Wylde Green, Birmingham B73 5LT. United Kingdom. Telephone +44 (0) 7880313315

Date Prepared: September 10th 2016

Date updated: March 22nd 2017

Device Trade Name: LIGHTFUSION™ LED System

Device Common name: Light based, non-laser device for wrinkles

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	Class 2	GEX	General & Plastic Surgery	Traditional 510 (k)

VITAGE LED System
Traditional 510(k)

Predicate device

The VITAGE LED system is substantially equivalent to the legally marketed device; Young Again LED mask **K124064.**

Device Description

The LIGHTFUSION™ LED system is a table top, portable phototherapy device whose purpose is to produce an even, cool, narrow-band of light for the treatment periorbital wrinkles.

The system consists of a main body or controller that controls the 3 LED face pads. The controller switches the LEDs ON/OFF and controls power to the face pads. The controller contains a timer display consisting of a Dot matrix display. The controller contains software that monitors the face pad temperature via thermistors within the face pads. The face pads contain the light emitting diodes (LEDs). The LEDs generate the light. The LEDs emit light energy in the red and near infrared light wavebands with peak wavelengths of 630nm +/-10nm, NIR: 830nm +/-17.5nm (Spectral range: Red 620-640nm, NIR 812.5-847.5nm). The therapy heads are designed to be placed over the forehead, sides of the face and chin.
The power supply 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 coaxial connector. The face pads are connected to the controller by individual connectors that are sealed within the controller and cannot be removed by the user. The face pads contain a temperature sensor (thermistor) that feeds the temperature back to the controller.
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.
LIGHTFUSION Light emitting diode (LED) system emits light energy in the red and near infra-red (NIR) region of the light spectrum and is intended to treat periorbital wrinkles through a non-thermal mechanism of Photobiomodulation. Photobiomodulation is a form of light therapy that utilizes non ionizing forms of light sources such as LEDs, in the visible and near infrared spectrum. It is a non thermal process involving endogenous chromophores eliciting photophysical and photochemical events at various biological scales.

Indications/Intended Use

The proposed intended use of the Lightfusion™ LED system is to emit energy in the RED and Near Infra-Red (NIR) regions of the spectrum and is indicated for the treatment of periorbital wrinkles.

Technological Characteristics

A comparative review of the VITAGE LIGHTFUSION LED System with the predicate device (Young Again k124064) found that the technologies, mode of operation, and general principles for treatment with this device was substantially equivalent.

Predicate comparison chart

Property	LIGHTFUSION LED system	K124064 Young again LED mask	Significant differences
Device Manufacturer	Vitage LED Ltd	Espansione Marketing Spa	na
Device Trade Name	LIGHTFUSION	Young again™	na
510(K) Number	-	K124064	na
Device Common Name	LIGHTFUSION	Young again™	na
Device Classification name	Laser surgical instrument for use in general and plastic surgery in Dermatology	Laser surgical instrument for use in general and plastic surgery in Dermatology	Identical
Device Product Code	GEX	OHS	Predicate is intended to be used by the consumer. LIGHTFUSION™ is intended to be used by suitably qualified professionals. Although the LIGHTFUSION system is NOT a laser the manufacturer thinks this is the closest applicable classification name.
Device Classification FDA	Class II	Class II	Identical
Use	Prescriptive	Over the Counter	Predicate is intended to be used by the consumer. LIGHTFUSION™ is intended to be used by suitably qualified professionals.
Intended use and Indications	The Lightfusion™ LED system is intended to emit energy in the RED and Near Infra-Red (NIR) regions of the spectrum and is indicated for the use in the treatment of periorbital wrinkles.	The Young again LED mask is an over the counter device intended to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles	Identical

VITAGE LED System
Traditional 510(k)

Property	LIGHTFUSION LED system	K124064 Young again LED mask	Significant differences
Mechanism of action	Non-thermal light energy in the red and near infra-red (NIR) region of the light spectrum is intended to treat periorbital wrinkles through a Photobiomodulatory effect.	Non-thermal light energy in the red and near infra-red (NIR) region of the light spectrum is intended to treat periorbital wrinkles through a Photobiomodulatory effect.	Identical
Intended Location of Use	Face	Face	Identical
Energy Type	Light emitting diodes	Light emitting diodes	Identical
Peak Wavelength (FWHM)	Red: 630nm+/-10nm. NIR: 830nm+/-17.5nm	Red: 634nm NIR:830nm	The output of the LIGHTFUSION™ LED system is within the predicates wavelength
Treatment protocol (Treatment time)	2 x weekly (10 minutes, 600 seconds) 4 weeks	2 x weekly (10 minutes, 600 seconds) 4 weeks	Identical
Intensity mW/cm²	Red 70mW/cm² NIR 55 mW/cm²	Red 70mW/cm² NIR 55 mW/cm²	Identical
Dose J/cm²	Red 42J/cm² NIR 33J/cm²	Red 42J/cm² NIR 33J/cm²	Identical
Timers	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	Identical

Non Clinical Performance & Safety Data:

To demonstrate safety and effectiveness and substantial equivalence the LIGHTFUSION™ LED system has undergone a number of non-clinical performance tests in line with recognised standards in terms of general requirements, biocompatibility, electrical safety and software.

General requirements and safety: The Light fusion LED system complies with IEC 60601-1: "Medical Electrical Equipment Part 1 - General Requirements for Basic Safety and essential performance" and IEC/EN 60601-1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and test.

VITAGE LED System
Traditional 510(k)

The LIGHTFUSION™ LED System has been evaluated against EN62471: Photobiological Safety of Lamps and Lamp Systems" in consideration of maximum possible light exposure to users and the results demonstrate that it poses no risk of retinal injury due to phototoxic effect, or the thermal damage mechanism. LIGHTFUSION™ LED System was assessed with regards to usability for compliance with IEC 62366: Medical devices - Application of usability engineering to medical devices.

Software: In accordance with IEC 62304: 2006 Medical device Software – software life cycle process Vitage LED Ltd has allocated a software safety classification of Class A for the LIGHTFUSION LED system. The software has also been classified using the FDA level of concern matrix and the level of concern for the device software is: **Minor**.

Biocompatability: Considering the intended use for the LIGHTFUSION™ LED system Vitage LED ltd believes that the device is safe and compliant with the requirements of ISO 10993 and the FDA - Blue Book Memorandum #G95-1in terms of biocompatibility. This position is supported by ISO 10993-1:2009 annex B.

These non-clinical tests demonstrate that the LIGHTFUSION™ LED system is safe and effective and performs at least as safely and effectively as the legally marketed predicate devices

Substantial Equivalence statement:

The intended use and technological characteristics of the LIGHTFUSION™ LED System are virtually identical to the intended use and technological characteristics of the listed predicate device. Differences between the LIGHTFUSION™ LED System and the predicate device raise no new questions of safety and efficacy and introduce no new risks.
The LIGHTFUSION™ LED System and its predicate device are light based devices that use non thermal red and near infrared light energy to treat periorbital wrinkles by exposing the surface of the skin to red and near infrared light and work through the non-thermal mechanism of photobiomodulation.
The systems share the same general indications for use, wavelengths and similar functional features. Any minor differences have been identified by the manufacturer and these have been negated by non - clinical performance testing.
VITAGE LED Ltd believe that the LIGHTFUSION™ LED system demonstrates substantial equivalence to the currently marketed predicate device, Young Again K124064.

Clinical Performance

Since the LIGHTFUSION™ LED system raises no new questions in terms of safety and efficacy clinical data is not required.