July 27, 2023

iSMART Developments Ltd
Susan D'arcy
Owner
129 Green Lanes, Boldmere, Sutton Coldfield
Birmingham, West Midlands B73 5LT
United Kingdom

Re: K231555
Trade/Device Name: LUMA LED patches (LUMA Blemish (TN2197) and LUMA Revive (TN2189))
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, OHS
Dated: May 30, 2023
Received: May 30, 2023

Dear Susan 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. 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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K231555

Device Name
LUMA LED light patches (LUMA Blemish and LUMA Revive)

Indications for Use *(Describe)*
The LUMA LED light patches are over-the-counter devices intended to emit energy in the visible and near infra-red light spectrum.

LUMA Blemish 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 of the face.

LUMA Revive is an over-the-counter device intended to emit energy in the red and Near infra-red spectrum and is intended for the use in the treatment of facial 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.

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Section 5: 510(k) Summary - K231555

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

Submitter's Name: ISMART DEVELOPMENTS LTD

Submitter's Address: 129 Green Lanes, Sutton Coldfield, Birmingham B73 5LT

Contact Person: Susan D'Arcy

Telephone: +44 (0) 7880313315

Date Prepared: May 21st 2023

Device Trade Name: LUMA LED patches (LUMA Blemish (TN2197) and LUMA Revive (TN2189))

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.	LUMA Blemish (TN2197) Over-The-Counter Powered Light-Based Laser for Acne	Class 2	OLP	General & Plastic Surgery	Traditional 510 (k)
	LUMA Revive (TN2189) Light Based Over the Counter Wrinkle Reduction		OHS		

5.1. Device Description

The LUMA Patches (Blemish and Revive) are battery operated, cordless wearable Light emitting diode (LED) devices intended to emit an even, cool, narrow band of light in the blue (415nm), red (630nm) and near infra-red (830nm) spectrum for the treatment of mild to moderate acne vulgaris and facial wrinkles. The devices work through non-thermal mechanisms called photobiomodulation (wrinkles) and endogenous Photodynamic therapy (acne vulgaris).

LUMA Blemish and LUMA Revive consists of the following key components.

1. Silicone flexible patches
2. Adhesive hydrocolloid patches x14
3. Magnetic 2 pin, 4mm to USB A connector
4. User manual

The LUMA patches are home use wearable LED phototherapy devices composed of flexible patches containing Light emitting diodes (LEDs). The LEDs generate the light.

The LUMA patches are comprised of an endo skeleton made of silicone containing an upper surface made of Polyurethane (PU) that houses the ON/OFF button magnetic charging pins and a battery charging indicator and a lower surface manufactured from Polyethylene terephthalate (PET).

The LEDs produce blue, red and near infra-red (NIR) light in the visible spectrum.

LUMA Blemish (Blue: 415nm +/- 10nm and Red: 630nm +/- 10nm)

LUMA Revive (Red: 630nm +/- 10nm and NIR 830nm +/-10nm.).

The LEDs are driven by an integrated 3.7V, 37mAh Lithium Polymer battery.

The battery is charged via a magnetic 2 pin, 4mm to USB A connector that plugs into a standard 5v USB A power adaptor. The device cannot be operated while in charging mode. The device contains a charging watchdog that prevents overcharge. The battery status of the devices is relayed to the user by a single indicator LED on the upper surface of the LUMA patches (during charging) and by the treatment LEDs on the lower or inner surface (during treatment).

The LUMA patches contain a simple ON/OFF button on the upper surface of the patch that switches the LEDs ON. The treatment time is 10 minutes. The devices automatically turn OFF after 600 seconds (10 minutes). The user may stop the treatment program during the 10 minutes by pressing the ON/OFF button.

The LUMA patches are worn on the face and are held in place by an adhesive hydrocolloid patch.

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

LUMA Blemish is an over-the-counter device intended to emit energy in the blue, and red region of the light spectrum and is indicated to treat mild to moderate acne vulgaris of the face.

LUMA Revive is an over-the-counter device intended to emit energy in the red and near infra-red region of the light spectrum and is indicated to treat full face wrinkles.

5.3. Substantial Equivalence

The LUMA Blemish and LUMA Revive are substantially equivalent to the primary predicate MZ Skin LightMAX Supercharged LED Mask 2.0 (K213184).

The LUMA Blemish and LUMA Revive are predicated against the MZ Skin LightMAX Supercharged LED Mask 2.0 (K213184) because they are both LED phototherapy devices intended to emit light in the red and blue and red and near infra-red region of the light spectrum and are indicated for the treatment of mild to moderate acne vulgaris and full-face wrinkles.

The LUMA Blemish and LUMA Revive are predicated against the LUSTRE PRO (K143713) as both devices are LED patches that are attached to the skin by way of an adhesive patch.

5.3.1. . Summary of Substantial Equivalence

Description	Subject device LUMA Blemish (TN2197) LUMA Revive (TN2189)	Primary K213184 MZ Skin LightMAX Supercharged LED Mask 2.0	Secondary K143713 Lustre PRO Light System	Significant differences
Device Manufacturer	ISMART Developments Ltd	MZ SKIN	Ambicare Health Ltd	na
Device Trade Name	LUMA patches (Blemish & Revive)	MZ Skin LightMAX Supercharged LED Mask 2.0	Lustre PRO Light System	na
510(K) Number		K213184	K143713	na
Device Classification name	Over-The-Counter Powered Light-Based Laser for Acne. Light Based Over the Counter Wrinkle Reduction	Over-The-Counter Powered Light-Based Laser for Acne. Light Based Over the Counter Wrinkle Reduction	Over-The-Counter Powered Light-Based Laser for Acne.	Identical
Device Product Code	OLP, OHS	OLP, OHS	GEX	Primary predicate is 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
FDA Device Classification	Class II	Class II	Class II	Identical

Description	**Subject device** **LUMA Blemish (TN2197)** **LUMA Revive (TN2189)**	**K213184** **MZ Skin LightMAX Supercharged LED Mask 2.0**	**K143713** **Lustre PRO Light System**	**Significant differences**
Use	Over the Counter	Over the Counter	Over the Counter	Identical
Intended use and Indications	LUMA Blemish 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 of the face. LUMA Revive is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	The MZ Skin LightMAX Supercharged LED Mask 2.0 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 of the face. The MZ Skin LightMAX Supercharged LED Mask 2.0 is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	The Lustre PRO Light system is intended to emit light in the blue region of the light spectrum and is indicated for the treatment of mild to moderate acne vulgaris.	Primary predicate is identical
Intended Location of Use	Face	Face	Face	Identical
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Identical
Peak Wavelength (FWHM)	Blue: 415nm +/- 10nm Red: 630nm +/- 10nm NIR 830nm +/-10nm	Blue: 415nm +/- 10nm Red: 630nm +/- 10nm NIR 830nm +/-10nm	415nm +/-15nm	Primary predicate is identical
Total Intensity (mW/cm^2)	LUMA Blemish (TN2197) 44 mW/cm^2	44 mW/cm^2	5mW/cm^2	Primary predicate is identical
	LUMA Revive (TN2189) 29 mW/cm^2	29 mW/cm^2		

Description	Subject device LUMA Blemish (TN2197) LUMA Revive (TN2189)	K213184 MZ Skin LightMAX Supercharged LED Mask 2.0	K143713 Lustre PRO Light System	Significant differences
Total Dose	LUMA Blemish (TN2197) 26.4/cm^2	26.4/cm^2	Blue 9J/cm^2	Primary predicate is identical
	LUMA Revive (TN2189) 18J/cm^2	18J/cm^2		
Treatment protocol	Acne: 4 x weekly, 6 weeks	Acne: 4 x weekly, 6 weeks	Daily for 4 weeks	Primary predicate is identical
	Wrinkles: 5 x weekly, 6 weeks	Wrinkles: 5 x weekly, 6 weeks		
Method of attachment	Single use adhesive patch	Held in place by 2 silicone straps	Single use adhesive patch	Substantially equivalent to secondary predicate
Software Controlled	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
Power supply	3.7V, 37mAh Lithium Polymer battery	5V, 9.62Wh Lithium Polymer battery	12V/1000mA Lithium-Ion battery	Primary predicate is identical

5.4. Substantial Equivalency and Comparison of Technological Similarities & Differences

5.4.1. Similarities between Subject devices and Primary predicate

From the comparative table above, the LUMA patches (LUMA Revive/LUMA Blemish) are substantially equivalent to the primary predicate device MZ Skin LightMAX Supercharged LED Mask 2.0 (K213184).

The key similarities are.

i. The intended use of the LUMA Blemish and LUMA Revive is equivalent to the MZ Skin LightMAX Supercharged LED Mask 2.0 an over-the-counter device that is intended for the use in the treatment of mild to moderate acne vulgaris and full-face wrinkles.

ii. The devices are phototherapy units utilizing light emitting diodes that emit in the red and blue spectrum for the treatment of mild to moderate acne vulgaris and the red and NIR spectrum for the treatment of full-face wrinkles.

iii. The wavelength spectrum of the devices is identical.

iv. The LUMA Patches have a similar power density and deliver similar doses of light that is substantially equivalent compared to the primary predicate device.

v. The LUMA patches have an identical treatment time and treatment protocol compared to the proposed primary predicate.

vi. All devices use software to control the treatment time.

5.4.2. Differences between Subject devices and Primary predicate

The only difference between the LUMA patches and the primary predicate MZ Skin LightMAX Supercharged LED Mask 2.0 (K213184) is the method of attachment to the treatment area. The primary predicate is held in place by adjustable straps whereas the LUMA patches are held in place by an adhesive patch. The use method of attachment is identical to K143713 Lustre PRO Light System in that both devices use a single use double sided adhesive patch that adheres to the LED device and to the treatment area. The LUMA patches are therefore substantially equivalent to the K143713 Lustre PRO Light System in method of attachment.

Where there are differences between the subject devices and the predicates these have been addressed by non-clinical performance testing to the applicable standards identified in section 5 of this document.

5.5. Non-clinical performance testing

The LUMA patches have been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]. Medical electrical equipment. General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 + IEC 60601-1-2:2014/A1:2020. Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests for: Home Healthcare Environment

47 CFR part 15b (FCC):2019 Electrical equipment for measurement, control, and laboratory use – EMC requirements - Part 1: General requirements. Conducted & Radiated Emissions- Class B

IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2021 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 60601-2-83:2020+A11 :2021. Medical electrical equipment – Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

IEC 60601-2-57:2011. Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

IEC 62471:2006-07. Photobiological safety of lamps and lamp systems.

IEC 62133 -2:2017-02. 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- Part 2: Lithium systems.

EN ISO 10993-1:2018. Biological evaluation of medical devices Part 1: Evaluation and testing

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

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

EN/IEC 62304 :2006 + IEC 62304 :2006/A1 :2015Medical Device Software- Software Life Cycle Processes

In addition to the above standards the LUMA patch 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 LUMA Blemish and LUMA revive were tested with an appropriate sample of users.

A study was conducted demonstrating comprehension of the LUMA patch labelling. Twenty-six subjects took part in the study, 12:14 M: F. The mean age of the study group was 31.7 years of age, with a range of 14 to 55 years old. Thirty eight percent of the group (n=10) identified English as a second language. The average number of words incorrect in the REALM was 7, giving a mean reading ability of 59 (High school) (range 43-66).

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 results of the human factors engineering process demonstrated that the packaging and labelling of the LUMA Blemish and LUMA Revive contained suitable information to allow the user to use the device safely and effectively for its intended purpose.

5.6. Clinical Performance

Since the LUMA patches are substantially equivalent to the predicate devices and raise no new questions in terms of safety and efficacy, clinical data is not required.

5.7. 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.

ISMART Developments Ltd has demonstrated that the LUMA patches have an identical intended use, have the same generic classification and basic principles

and technologies as the primary predicate device (K213184)**.** The devices utilize red and blue wavelengths of light with similar power densities and equivalent cumulative dose for the treatment of mild to moderate acne vulgaris and red and NIR of light with similar power densities and equivalent cumulative dose for the treatment of full-face wrinkles.

The LUMA patches have an identical mechanism of attachment to the treatment area as the secondary predicate device (K143713).

ISMART Developments 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 LUMA Blemish and LUMA Revive raise no additional questions relating to safety. The LUMA Blemish and LUMA Revive are as safe and effective and performs as well as or better than the legally marketed predicate devices K213184 and K143713.