September 12, 2019

iSMART Marketing SVCS Ltd
Susan D'Arcy
Director/Owner
129 Green Lanes, Sutton Coldfield
Birmingham, B735LT GB

Re: K191629
Trade/Device Name: faceLITE
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: June 12, 2019
Received: June 19, 2019

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 post-marketing 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,

Purva Pandya
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)*
K191629

Device Name
faceLITE LED mask

Indications for Use *(Describe)*
The faceLITE LED mask is an over the counter device that is intended for the use in the treatment of full-face 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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faceLITE
FROM THE NATURAL FACELIFT COMPANY

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: Ismart Marketing SVCS Ltd.

Submitter's Address: 129 Green Lanes, Sutton Coldfield, Birmingham B735LT

SBDN: SBD195544

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

Date Prepared: June 12th, 2019

Date Amended: September 9th, 2019

Device Trade Name: faceLITE LED mask

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.	Light Based Over the Counter Wrinkle Reduction	Class 2	OHS	General & Plastic Surgery	Traditional 510 (k)

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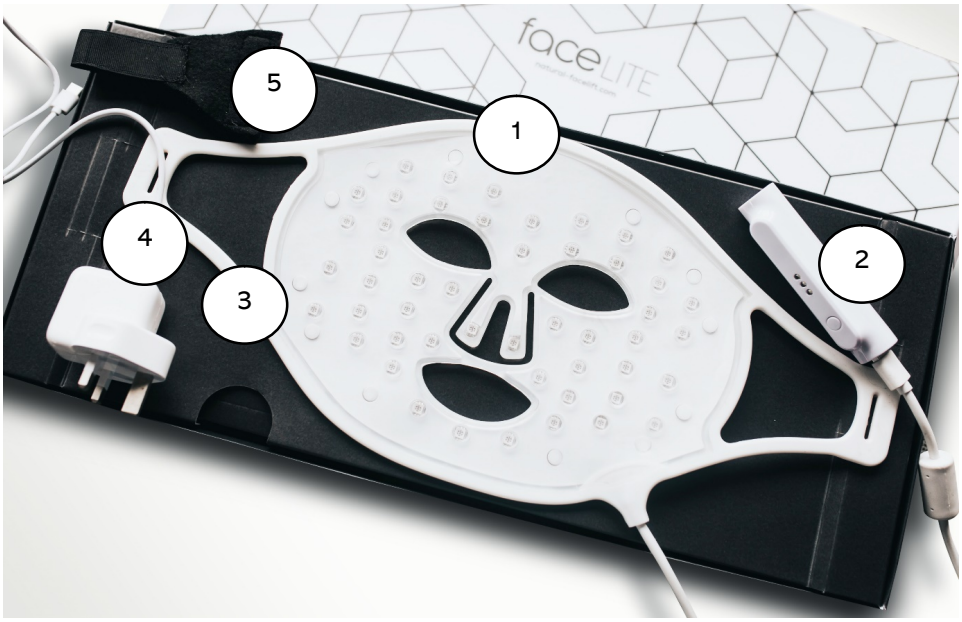
5.1. Device Description

5.1.1. Overall Description

The faceLite consists of;

1. Silicon flexible face mask
2. Controller
3. Power supply and country specific adaptors
4. USB C to USB A connector
5. Head straps



faceLite is a home use wearable LED phototherapy device whose purpose is to produce an even, cool, narrow band of light for the treatment cosmetic indications including facial wrinkles.

The system consists of a flexible silicon mask that contains light emitting diodes (LEDs) and a controller. The LEDs generate the light. The mask is worn on the face and is held in place by an adjustable Velcro strap. The mask compromises of 2 surfaces. An inner surface that contacts the skin and an outer surface. Both surfaces are constructed of the same silicone (Methyl vinyl silicone rubber, Genvan GA 3 series GA9 series).

The inner surface contacts with the user's skin. Contact is restricted to normal intact skin and only for a duration of 10 minutes (treatment time). Methyl vinyl silicone rubber GENVAN GA 3 series GA9 series has been tested to those tests specified under ISO 10993-5:2009 tests for in vitro cytotoxicity and ISO10993-10:2010 Tests for irritation and skin sensitization

The controller (Polycarbonate PC1100) switches the LEDs ON/OFF and controls power to the mask. The controller contains a rechargeable Lithium ion polymer battery. The controller

uses a visible display comprising of 3 micro LEDs to show the user the battery charge status of the device.

The power supply (SK01T-0500100Z) is used to charge the Lithium battery and 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 micro USB A-C connector. The faceLite cannot be operated while charging.

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.

The faceLite 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 facial wrinkles through a non-thermal mechanism called Photobiomodulation.

5.2. Intended Use

The faceLITE™ LED mask emits light in the red and near infra-red (NIR) region of the light spectrum and is indicated for the treatment of full face wrinkles.

5.3. Substantial Equivalence

The faceLITE LED mask is substantially equivalent to the LG BEAUTY LED MASK (K170984).
The faceLITE LED Mask is predicated against the LG Beauty LED mask because both masks are LED phototherapy devices intended to emit light in the red and near infra-red region of the light spectrum and indicated for the treatment of full-face wrinkles.

5.3.1 Summary of Substantial Equivalence

Property	faceLITE LED mask	K170984 LG Beauty LED mask	Significant differences
Device Manufacturer	iSMART Marketing SVCS Ltd	LG Electronics, Inc.	na
Device Trade Name	faceLITE™	LG Beauty™	na
510(K) Number	-	K170984	na
Device Common Name	faceLITE™	LG Beauty™	na

faceLITE
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Property	faceLITE LED mask	K170984 LG Beauty LED mask	Significant differences
Device Classification name	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	Identical
Device Product Code	OHS	OHS	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.	Identical
FDA Device Classification	Class II	Class II	Identical
Use	Over the Counter	Over the Counter	Identical
Intended use and Indications	The faceLITE LED mask is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	The LG BEAUTY LED MASK is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	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+/-10nm	Red: 637nm NIR:854nm	The output of the FaceLITE™ LED mask is within the predicate's wavelength
Intensity	30mw/cm^2 total	25 mW/cm^2 total	Similar
Treatment time	600 seconds	540 seconds	Similar
Treatment protocol (Treatment time)	5 x weekly, 6 weeks	5 x weekly, 8 weeks	Similar

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Property	faceLITE LED mask	K170984 LG Beauty LED mask	Significant differences
Cumulative dose	540J/cm^2	540J/cm^2	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

5.3.2. Substantial Equivalency and Comparison of Technological Similarities & Differences

From the comparative table above, the faceLITE LED Mask demonstrates equivalence to the LG Beauty LED mask. The key similarities are;

i. The intended use of the faceLITE LED mask is equivalent to the listed predicate; an over the counter device that is intended for the use in the treatment of full-face wrinkles.
ii. Both devices are phototherapy units utilizing light emitting diodes that emit in the red and near infra-red-light spectrum.
iii. Both devices have a similar power density and deliver an identical cumulative dose and have similar treatment protocols.

5.4. Non- clinical performance testing

The faceLITE LED system has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards;

IEC/EN 60601-1: 2006 + A12:2014 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
IEC/EN 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
EN 60601-1-6: 2010. AMD12013 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 60601-1-11:2015 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

IEC60601-2-57 1st ed: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 Photobiological safety of lamps and lamp systems.

IEC62133:2012 2nd ed. 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

ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.

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

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

EN 62304: 2006 (ed. 1.0) Medical Device Software - Software Life Cycle Processes.

ISO 14971: 2012 Medical Devices - Application of Risk Management to Medical Devices

In addition to the aforementioned standards the faceLITE labelling was subject to label comprehension testing. With respect to medical devices available without the intervention of a physician, termed 'Over the Counter' (OTC), the labelling and instructions for use (IFU or User Guide)) must convey to the consumer enough information to allow them to safely operate the device to attain its purpose. To determine the effectiveness of labelling pertaining to a medical device, the labelling and device was tested with an appropriate random sample of users.

A study was conducted and is appended to this section demonstrating comprehension of the faceLITE labelling. 32 subjects took part in the study. The average age of the participants was 35 years of age. Fifty nine percent (59%) of subjects were female (13:19, M:F ratio). In terms of ethnicity 18 subjects classed themselves as Caucasian and 14 non-Caucasian (Black: 4, Hispanic: 6, Indian: 2, Asian: 2). Seven (22%) of subjects indicated that English was their second language. REALM reading tests were conducted.

The comprehension and use test demonstrated that the faceLITE labelling could be used by lay persons to safely and effectively operate the device to attain its intended use and purpose.

faceLITE
FROM THE NATURAL FACELIFT COMPANY

Clinical Performance

Since the faceLITE LED mask raises no new questions in terms of safety and efficacy, clinical data is not required.

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 Marketing SVCS Ltd has demonstrated that the faceLITE LED mask has an identical intended use, have the same generic classification and basic principles and technologies as the predicate device**.** Both devices utilize red and NIR wavelengths of light with similar power densities and identical cumulative dose.

iSMART Marketing SVCS Ltd 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 faceLITE LED mask raises no new questions relating to safety and therefore has demonstrated that the faceLITE LED mask is substantially equivalent to the referenced predicate LG Beauty mask (K170984).

June 12th, 2019