November 8, 2024

ISMART Developments Ltd
Susan D'arcy
Owner
129 Green Lanes
Wylde Green
Birmingham, B73 5LT
United Kingdom

Re: K242382
Trade/Device Name: décoLITE LED Device
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 12, 2024
Received: August 12, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.11.08 12:20:17 -05'00'

for Tanisha Hithe
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242382

Device Name
décoLITE

Indications for Use *(Describe)*
The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the decolletage area.

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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510(k) Summary

K242382

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, Wylde Green, Birmingham, B73 5LT United Kingdom
Contact Person:	Susan D'Arcy
Telephone:	+44 (0) 7880313315
Date Prepared:	October 9, 2024
Device Trade Name:	décoLITE Light-Emitting Diode (LED) Device (TN2037)
Common Name:	Light Based Over the Counter Wrinkle Reduction
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Product Code:	OHS
Review Panel:	General & Plastic Surgery

Predicate Device

K191629	faceLITE LED Mask

Intended Use

The décoLITE light emitting diode (LED) device emits light energy in the red and near infrared (NIR) regions of the light spectrum and is intended for the treatment of wrinkles in the décolletage area.

Device Description

The décoLITE device consists of:

1. Flexible silicone panel
2. Controller
3. Power supply and country specific adaptors
4. Adjustable straps (2)

décoLITE is a home use wearable light emitting diode (LED) phototherapy device.

The device consists of a flexible silicone panel (1) that contains red (630nm) and near infrared (830nm) light emitting diodes (LEDs), a controller (2) that contains a rechargeable lithium polymer batter, a power supply (3) for charging the battery, and two adjustable straps (4) that hold the panel in place during treatment.

The LEDs produce red and near infrared (NIR) light in the visible spectrum (Red: 630nm ± 10nm, NIR: 830nm ± 10nm). The device works through a non-thermal mechanism called photobiomodulation. The LEDs produce light at an intensity of 30mW/cm^2 delivering 18J/cm^2 per treatment.

The power supply is used to charge the lithium polymer battery in the décoLITE controller

Substantial Equivalence Discussion

The décoLITE LED Device is substantially equivalent to the faceLITE LED mask (K191629).

Description	**Subject device (K242382)** **décoLITE (TN2037)**	**K191629** **faceLITE LED mask**	**Comparison**
Device Manufacturer	ISMART DEVELOPMENTS LTD	iSMART Marketing SVCS Ltd	N/A
Device Trade Name	décoLITE	faceLITE™	N/A
Device Classification name	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	Same
Device Product Code	OHS	OHS	Same
Regulation	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.	Same
Device Classification	Class II	Class II	Same
Rx/OTC	Over the Counter	Over the Counter	Same
Intended Use and Indications for Use	The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the decolletage area.	The faceLITE LED mask is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	Similar, different anatomical location.

Description	Subject device (K242382) décoLITE (TN2037)	K191629 faceLITE LED mask	Comparison
Intended Location of Use	Decolletage (upper chest)	Face	Different
Energy source	Light emitting diodes	Light emitting diodes	Same
Peak Wavelength (FWHM)	Red: 630nm ± 10nm NIR: 830nm ± 10nm	Red: 630nm ± 10nm NIR: 830nm ± 10nm	Same
Intensity	30mW/cm^2 total	30mW/cm^2 total	Same
Treatment time	600 seconds (10 minutes)	600 seconds (10 minutes)	Same
Treatment protocol	5× weekly, 6 weeks	5× weekly, 6 weeks	Same
Cumulative dose	540J/cm^2	540J/cm^2	Same
Timers	Devices uses a timer and software to control treatment duration.	Devices uses a timer and software to control treatment duration.	Same
Software Controlled	Yes	Yes	Same

The Subject device has been subjected to clinical performance testing to assess the safety and effectiveness of the device in treating wrinkles of the decolletage area as described below.

Electrical Safety Testing

décoLITE was designed to meet applicable industry standards for electromagnetic compatibility (EMC) and electrical safety.

The device relies on standards identified for Medical Electrical Equipment which ensure that the product is safe and effective for its intended use regarding EMC and electrical safety.

décoLITE has been tested and found to comply with the following applicable standards:

1. IEC 60601-1:2005/(R)2012 & A1:2012, [Incl. AMD2:2020]. Medical electrical equipment. General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014 + IEC 60601-1-2:2017. 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
3. 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.
4. 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
5. IEC 60601-2-83:2019. Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
6. IEC 62133-2:2017. 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.

Non-Clinical Performance Testing

Eye Safety

décoLITE has been tested to and complies with IEC 62471:2006, Photobiological safety of lamps and lamp systems.

Thermal safety

During normal operation with a treatment time of 10 minutes the change in skin temperature from baseline to the end of treatment is +1°C for décoLITE, with a mean skin temperature of 35.5°C at the end of normal treatment. The panel surface, when in contact with the skin, increases from baseline by +1.1°C, with a mean surface temperature of 34.6°C at the end of normal treatment.

Light characteristics.

Test results verified the output characteristics of the devices.

Usability/Human factors

The décoLITE labeling was subject to label comprehension testing (IEC 62366-1:2015+A1:2020, Application of usability engineering to medical devices)

Seventeen subjects took part in the study, 5 male and 12 female. Eight subjects were Caucasian, 4 were Asian, and 5 were Hispanic. Six subjects identified English as a second language The mean age of the study group was 43 years of age, with a range of 24 to 58 years old. The average REALM (Rapid Estimate of Adult Literacy in Medicine) words incorrect was 7.3, with an average REALM

score of 58.7, which represented 7th-8th grade. Two subjects presented with a REALM score of 4th-6th grade, 10 with a 7th-8th grade score and the remaining 5 had a score of high school.

All seventeen subjects were able to complete all tasks by following the device's labelling, including instructions for use. Per the definitions of IEC 62366-1:2015+A1:2020, all tasks were performed within correct or normal use by all subjects.

Observations of tasks that were not completed exactly as specified in the labelling were within the bounds of normal use and did not pose additional hazards.

Clinical Performance Testing

A clinical study was conducted to support the safety and effectiveness of the décoLITE LED device in treating wrinkles of the chest.

The objective of the study was to assess the safety and effectiveness of the décoLITE LED device in reducing wrinkling of the décolletage (upper chest). The treatment course for the study was 5 treatment sessions per week (on separate days), 10 minutes each, for 6 weeks. After the initial visit, treatment sessions were conducted by the subject at home, The primary effectiveness endpoint of the study was a reduction in décolleté lines after a completing a course of light therapy, measured using the validated scale developed by Landau et al. (2016).[1]

Twenty-five (n=25) subjects were enrolled in the study. Six subjects withdrew from the study; three of these subjects were lost to follow-up, two were unable to continue treatments for personal reasons unrelated to the study, and one was unwilling to return to the clinic for images. Nineteen subjects completed the full study treatment course. After identifying unprotected sun exposure in one of these 19 subjects, their results were excluded.

The average age of the group was 54 (range 38 to 65), and the group comprised entirely of females. Fitzpatrick skin types II, III, IV, and V were included. Of the 25 subjects, 22 identified as White/Caucasian, 2 identified as Hispanic or Latino, and 1 identified as Asian.
No adverse events were reported. The mean baseline wrinkle severity was 2.5 and the mean improvement after treatment was 0.9 points. Sixteen of 19 subjects (84%) felt their wrinkles had improved and 16 of 19 subjects (84%) felt the overall appearance of their chest had improved. 16 of 19 subjects (84%) felt the overall appearance of their chest had improved.

Conclusions

iSMART Developments LTD has demonstrated that the décoLITE LED Device has an equivalent Intended Use, classification, and technological characteristics as the predicate device and is used with the same treatment regimen. The decoLITE LED is intended for use on a different body area. Clinical performance testing demonstrated improvement and no safety concerns. Therefore, the décoLITE LED Device is substantially equivalent to the referenced predicate faceLITE LED mask (K191629).

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[1] Landau, M., et al. (2016, July). Validated Assessment Scales for Décolleté Wrinkling and Pigmentation. *Dermatologic Surgery, 42*(7), 842-852.