March 22, 2022

Harpar Grace International
% Susan D'arcy
Owner
iSMART Developments Ltd
129 Green Lanes, Sutton Coldfield
Birmingham, B735TR
United Kingdom

Re: K214103
Trade/Device Name: Shani Darden LED light therapy mask
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: December 24, 2021
Received: December 29, 2021

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,

Purva Pandya
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)*
K214103

Device Name
Shani Darden LED light therapy mask

Indications for Use *(Describe)*
The Shani Darden LED light therapy mask 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 Shani Darden LED light therapy mask 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.

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

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

Submitter's Name: Harpar Grace International (HGI)
Submitter's Address: Unit 4 Imperial Court, Magellan Close, Walworth Business Park, Hampshire. SP10 5NT
Contact Person: Alana Marie Chalmers
Telephone: +44 (0) 2038686242

Date Prepared: December 24th, 2021
Date amended: March 21st, 2022
Device Trade Name: Shani Darden LED light therapy mask

Device Classification Information:

Regulation Number	Classification Name	Common 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	Over-The-Counter Light-Based treatment for Acne and Wrinkle Reduction	Class 2	OLP OHS	General & Plastic Surgery	Traditional 510 (k)

5.1. Device Description

The Shani Darden LED light therapy mask consists of the following key components.

1. Facemask
2. Controller
3. Power supply and country specific adaptors
4. Velcro strap
5. User manual
6. Carry Bag

The Shani Darden LED light therapy mask is a home use wearable light emitting diode phototherapy device whose purpose is to produce an even, cool, narrow band of light for the treatment of full-face wrinkles and mild to moderate acne vulgaris of the face.

The system consists of a hard-shell mask (1) and a controller (2). The outer shell of the mask is manufactured from Acrylonitrile butadiene styrene (ABS) CHIMEI 757KF. The inner shell is a clear Polycarbonate CHIMEI PC115P. The Light emitting diodes are mounted behind the clear Polycarbonate. The LEDs generate the light.

The mask is worn on the face and is held in place by an adjustable Velcro strap (5). The LEDs produce blue, red and near infra-red (NIR) light in the visible spectrum (Blue: 415nm +/- 10nm, Red: 630nm +/- 10nm, NIR 830nm +/-10nm.). The device works by emitting the specified wavelengths into the skin in order to improve the appearance of wrinkles or to target bacteria that can cause acne vulgaris.

The controller (2) allows the user to select one of three treatment programmes (acne and wrinkles) and switches the LEDs ON/OFF, controlling power to the mask. The controller contains a simple graphical user interface (GUI) and three control buttons.

1. Standby Button: wakes the device up from Sleep mode

2. Mode Button: Allows the user to select treatment modes.

3. Start button. Allows the user to start and pause a treatment

The GUI shows the treatment mode selected and a countdown timer that counts downs from 10 minutes in 1-minute increments.

The mask receives its power from a mains power adaptor (Input 100v-240v. 50/60hZ. Rated at 0.7A) Output (12V, 1A).

The power adaptor is connected to the controller by a standard USB A connector.

The Shani Darden LED light therapy mask does NOT contain or does NOT rely on external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.).

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

The Shani Darden LED light therapy mask 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 Shani Darden LED light therapy mask 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.

5.3. Predicate device

K213184 MZ Skin LightMAX Supercharged LED Mask 2.0

5.3.1 Summary of Substantial Equivalence

Description	Shani Darden LED light therapy mask	K213184 MZ Skin LightMAX
Device Manufacturer	Harpar Grace International	MZ SKIN
Device Trade Name	Shani Darden LED light therapy mask	MZ Skin LightMAX Supercharged LED Mask 2.0
510(K) Number	K214103	K213184
Device Product Code	OLP, OHS	OLP, OHS
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
FDA Device Classification	Class II	Class II
Use	Over the Counter	Over the Counter
Intended use and Indications	The Shani Darden LED light therapy mask 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 Shani Darden LED light therapy mask 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.

Description	Shani Darden LED light therapy mask	K213184 MZ Skin LightMAX
Intended Location of Use	Face	Face
Energy Type	Light emitting diodes	Light emitting diodes
Peak Wavelength (FWHM)	Blue: 415nm +/- 10nm, Red: 630nm +/- 10nm, NIR 830nm +/-10nm.	Blue: 415nm +/- 10nm, Red: 630nm +/- 10nm, NIR 830nm +/-10nm.
Intensity (mW/cm^2)	Blue 28 mw/cm^2 Red 16 mw/cm^2	Blue 28 mw/cm^2 Red 16 mw/cm^2
	Red 18 mw/cm^2 NIR 11 mw/cm^2	Red 18 mw/cm^2 NIR 11 mw/cm^2
Total Intensity (mW/cm^2)	Blue/Red 44 mw/cm^2	Blue/Red 44 mw/cm^2
	Red/NIR 29 mw/cm^2	Red/NIR 29 mw/cm^2
Treatment time	10 Minutes	10 Minutes
Dose	Blue 16.8J/cm^2 Red 9.6J/cm^2	Blue 16.8J/cm^2 Red 9.6J/cm^2
	Red 11J/cm^2 NIR 7J/cm^2	Red 11J/cm^2 NIR 7J/cm^2
Treatment protocol	Acne: 4 x weekly, 6 weeks	Acne: 4 x weekly, 6 weeks
	Wrinkles: 5 x weekly, 6 weeks	Wrinkles: 5 x weekly, 6 weeks
Software Controlled	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration

Description	Shani Darden LED light therapy mask	K213184 MZ Skin LightMAX
Power supply	100-240V	Lithium-Ion Battery (rechargeable)
Power input/output	Electrical Input to power adaptor: 100v-240v. 50/60Hz. Rated at 0.7A. Electrical Output from power adaptor: 12V, 1A	Electrical Input from power adaptor: 100-240Vac/47-63Hz. 0.6A Electrical Output; 5V, 9.62Wh or 2200mAH

5.3.2. Comparison of Technological Similarities & Differences

The key similarities are.

i. The intended use of the Shani Darden LED light therapy mask is the same as the listed predicate; 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 similar.
iv. The Shani Darden LED light therapy mask has similar power density and dose to the predicate device.
v. The Shani Darden LED light therapy mask has an identical treatment time and treatment protocol compared to the proposed predicate.
vi. Both devices use software to control the treatment time.

The key difference between the Shani Darden LED light therapy mask and predicate device is that the sponsor device uses a power adaptor to control power while the predicate device utilizes Lithium-Ion batteries. This difference has been addressed by EMC and electrical safety testing. Where other differences exist, these have been addressed by non-clinical performance testing to applicable standards.

5.4. Non- clinical performance testing

The Shani Darden LED light therapy mask has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.
IEC 60601-1:2005/AMD1:2012/AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
IEC/EN 60601-1-2: 2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests including FCC 47 CFR Part 15, Sub Part B
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.
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 62471:2008. Photobiological safety of lamps and lamp systems.
ISO 10993-1: 2018 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: 2019 Medical Devices - Application of Risk Management to Medical Devices

In addition to the above standards the Shani Darden LED light therapy mask 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 device was tested with an appropriate sample of users.

A study was conducted and is appended to this submission, demonstrating comprehension of the Shani Darden LED light therapy mask labelling.

Nineteen subjects took part in the study, 8:11 M:F, average age 31.6 years (range 16-57). Eight subjects identified English as their second language. In terms of ethnicity 6 subjects identified as Hispanic, 3 Asian, and 1 Indian. The average number of words incorrect in the REALM reading test was 9, giving a mean reading ability of 57 (7^{th} grade).

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 comprehension and use test demonstrated that the Shani Darden LED light therapy mask labelling could be used by lay persons to safely and effectively operate the device to attain its intended use and purpose.

Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

Conclusion

The Shani Darden LED light therapy mask utilizes the same light-emitting technological characteristics as the predicate device, and the new device does not raise new types of questions regarding safety and efficacy when compared to the predicate device. The device has been tested as described above to show that the device can be used safely and effectively. The Shani Darden LED light therapy device is considered to be substantially equivalent to the predicate device K213184.