November 23, 2021

Mz Skin
% Susan D'arcy
Owner
iSMART Developments Ltd
129 Green Lanes, Sutton Coldfield
Birmingham, B735TR
United Kingdom

Re: K213184
Trade/Device Name: MZ Skin LightMAX Supercharged LED Mask 2.0
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: September 26, 2021
Received: September 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 and Part 809); 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)*
K213184

Device Name
MZ Skin LightMAX Supercharged LED Mask 2.0

Indications for Use *(Describe)*
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.

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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510(k) Summary

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

Submitter's Name: MZ SKIN LTD

Submitter's Address: 110-112 Kings Road, First floor, SW3 4TX, London, UK

Contact Person: Maryam Zamani MD

Telephone: +44 (0)20 3409 1479

Date Prepared: November 8th, 2021

Device Trade Name: MZ Skin LightMAX Supercharged LED Mask 2.0

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 MZ Skin LightMAX Supercharged LED Mask 2.0 consists of.

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

The MZ Skin LightMAX Supercharged LED Mask 2.0 (LightMAX) is a home use wearable light emitting diode (LED) 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 flexible silicon mask and a controller. The flexible silicon mask is manufactured from (Genvan GA 3-9) and contains the light emitting diodes (LEDs) The LEDs generate the light. The mask is worn on the face and is held in place by adjustable Velcro straps.

The LEDs produce blue, red and near infra-red (NIR) light in the visible spectrum (Blue: 412.5nm +/- 7.5nm, Red: 630nm +/- 10nm, NIR 830nm +/-15nm.). The device works through non-thermal mechanisms called Photobiomodulation (wrinkles) and endogenous Photodynamic therapy (acne vulgaris).

The controller (ABSKF757 / Polyac-757) allows the user to select one of two treatment programmes (acne or wrinkles) and switches the LEDs ON/OFF, controlling power to the mask. The programs are selected by the user pressing and holding the appropriate power button. The controller contains a countdown timer that activates once the user has selected the appropriate treatment program and counts down from 10:00 minutes. The user may stop the treatment program during the 10 minutes by pressing the appropriate ON/OFF button.

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 (3) input socket and wall plug. The power cable is connected to the controller by a standard micro–USB A-C connector. The MZ Skin LightMAX Supercharged LED Mask 2.0 cannot be operated while charging.

The mask compromises of 2 surfaces. An inner clear 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 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. Indications for Use

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.

5.3. Predicate devices

Omnilux CLEAR (K210948) Globalmed Technologies

faceLITE (K191629) iSMART Marketing Svcs Ltd

5.4 Comparison Characteritics

Description	MZ Skin LightMAX Supercharged LED Mask 2.0	K210948 Omnilux CLEAR	K191629 faceLITE	Significant differences
Device Manufacturer	MZ SKIN	Globalmed Technologies	iSMART Developments Ltd	na
Device Trade Name	MZ Skin LightMAX Supercharged LED Mask 2.0	Omnilux CLEAR™	faceLITE™	na
510(K) Number	K213184	K210948	K191629	na
Device Product Code	OLP, OHS	OLP	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.	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
Use	Over the Counter	Over the Counter	Over the Counter	Identical

Description	**MZ Skin LightMAX Supercharged LED Mask 2.0**	**K210948 Omnilux CLEAR**	**K191629 faceLITE**	**Significant differences**
Intended use and Indications	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 Omnilux CLEAR acne facemask 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 faceLITE LED mask is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	Identical to the individual predicates
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.	Red: 630nm +/- 5nm. Blue: 412.5nm +/- 7.5nm	Red: 630nm+/-10nm. NIR: 830nm+/-10nm	Similar
Intensity (mW/cm^2)	Blue 28 mw/cm^2 Red 16 mw/cm^2	Blue 28 mw/cm^2 Red 16 mw/cm^2	-	Identical
	Red 18 mw/cm^2 NIR 11 mw/cm^2	-	Red 15 mw/cm^2 NIR 15 mw/cm^2	Similar

Description	**MZ Skin LightMAX Supercharged LED Mask 2.0**	**K210948 Omnilux CLEAR**	**K191629 faceLITE**	**Significant differences**
Total Intensity (mW/cm^2)	Blue/Red 44 mw/cm^2	44 mw/cm^2	-	Identical
	Red/NIR 29 mw/cm^2	-	30 mw/cm^2	Similar
Treatment time	10 Minutes	10 Minutes	10 minutes	Identical
Dose	Blue 16.8J/cm^2 Red 9.6J/cm^2	Blue 16.8J/cm^2 Red 9.6J/cm^2	-	Identical
	Red 11J/cm^2 NIR 7J/cm^2	-	Red 9J/cm^2 NIR 9 J/cm^2	Similar
Treatment protocol	Acne: 4 x weekly, 6 weeks	4 x weekly, 6 weeks	-	Identical
	Wrinkles: 5 x weekly, 6 weeks	-	5 x weekly, 6 weeks	Identical
Timers	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
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

5.3.2. Comparison of Technological Similarities & Differences

From the comparative table above, the MZ Skin LightMAX Supercharged LED Mask 2.0 is the same or similar to the predicate devices, Omnilux CLEAR (K210948) and faceLITE (K191629) LED facemasks.

The key similarities are.

i. The intended use of the MZ Skin LightMAX Supercharged LED Mask 2.0 is the same as the listed predicates; 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 the same.

iv. The MZ Skin LightMAX Supercharged LED Mask 2.0 device has similar power density and delivers a similar dose to the predicate devices.

v. The MZ Skin LightMAX Supercharged LED Mask 2.0 has an identical treatment time and treatment protocol compared to the proposed predicates.

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

There are therefore no significant differences between the proposed device and predicate devices. Where there are differences, these have been addressed by non-clinical performance testing to the following applicable standards

5.4. Non- clinical performance testing

The MZ Skin LightMAX Supercharged LED Mask 2.0 system has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 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 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 62471:2008. 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: 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: 2012 Medical Devices - Application of Risk Management to Medical Devices

The software of the MZ Skin LightMAX Supercharged LED Mask 2.0, utilizes simple software, similar to the predicate devices. In accordance with FDA Guidelines the firmware used in the LightMAX Supercharged LED Mask 2.0 has been categorised by the sponsor as a MINOR level of concern (failures or latent design flaws are unlikely to cause any injury to the patient or operator).In accordance with IEC 62304: 2006 Medical device Software – software life cycle process and based on the risk analysis and associated mitigations Verification and Validation of the firmware/software provides evidence that the final software has been fully tested and pass the specified acceptance criteria and meets all requirements enabling the device to be safely used for its intended purpose.

In addition to the above standards the MZ Skin LightMAX Supercharged LED Mask 2.0 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 random sample of users.

A study was conducted and is appended to this submission, demonstrating comprehension of the MZ Skin LightMAX Supercharged LED Mask 2.0 labelling. 24 subjects took part in the study, 11:14 M:F, average age 31.5 years (range 16-61).

Seven subjects identified English as their second language. In terms of ethnicity 6 subjects identified as Hispanic, 1 African American, 2 Asian, and 1 Indian. The average number of words incorrect in the REALM reading test was 7, giving a mean reading ability of 59 (7^{th} – 8^{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 MZ Skin LightMAX Supercharged LED Mask 2.0 labelling could be used by lay persons to safely and effectively operate the device to attain its intended use and purpose.

Conclusion

MZ SKIN has demonstrated that the MZ Skin LightMAX Supercharged LED Mask 2.0 has an identical intended use, has the same generic classification and basic principles and technologies as the predicate devices**.** 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.

MZ SKIN 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 MZ Skin LightMAX Supercharged LED Mask 2.0 does not raise additional questions relating to safety and therefore has demonstrated that the MZ Skin LightMAX Supercharged LED Mask 2.0 is as safe and as effective as and performs as well as the referenced predicate devices Omnilux CLEAR (K210948) and faceLITE (K191629) LED facemasks.