December 20, 2022

Light Tree Ventures Europe B.V.
℅ Alain Dijkstra
Official Correspondent
Shenzhen Kaiyan Medical Equipment Co., Ltd
Building 3, No. 40, Fuxin street, Huaide Community
Fuyong Town, Baoan District
Shenzhen, Guangdong 518103
China

Re: K221775
Trade/Device Name: LED Light Therapy Mask (model: MK-78, MK-04, MK66-H, EL00003)
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, OLP
Dated: October 21, 2022
Received: October 21, 2022

Dear Alain Dijkstra:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221775

Device Name
LED Light Therapy Mask (Model: MK-78, MK-04, MK66-H, EL00003)

Indications for Use *(Describe)*
For MK-78, MK-04,
The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.

For MK66-H, EL00003
The LED Light Therapy Mask (Models: MK66-H, EL00003) 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 LED Light Therapy Mask (Models: MK66-H, EL00003) 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 for K221775

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Light Tree Ventures Europe B.V.
Establishment Registration Number: 3017422691
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E-mail: regulation@kaiyanmedical.com

Manufacturer:

Manufacturer Name: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
Address: Building 3, No.40, Fuxin street, Huaide Community, Fuyong Town, Baoan District, Shenzhen, Guangdong, 518103, China
Contact Person (including title): Alain Dijkstra (CEO)
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Fax: 0755-25024651
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Application Correspondent:

Contact Person: Alain Dijkstra
Company: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
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2. Date of the summary prepared: December 19, 2022

3. Subject Device Information

Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)

Trade Name: LED Light Therapy Mask
Model Name: MK-78, MK-04, MK66-H, EL00003
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Harpar Grace International
Trade Name: Shani Darden LED light therapy mask
Classification Name: Over-the-counter powered light based laser for acne
510(K) Number: K214103
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulation Class: II

Predicate Device 2 Information

Sponsor: ISMART Marketing Svcs Ltd
Trade Name: FaceLITE
Classification Name: Light based over the counter wrinkle reduction
510(K) Number: K191629
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 878.4810
Regulation Class: II

5. Device Description

The LED Light Therapy Mask is a home 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, or mild to moderate acne vulgaris of the face.

The system consists of a flexible silicone mask that contains LEDs and a controller. The mask is worn on the face and is held in place by adjustable Velcro straps. The mask compromises of 2 surfaces. An inner surface that contacts the skin and an outer surface. Both surfaces are constructed of silicone.

The controller contains a rechargeable Lithium battery, the power supply (adaptor) 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 LED Light Therapy Mask cannot be operated while charging.

The device is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The device does not require checks on the light output as the LEDs do not dim with age to any practical extent.

Models MK-78, and MK-04 produce red and near infra-red (NIR) light in the visible spectrum (Red: 630+/- 5nm, NIR: 830nm) in intended to improve the appearance of wrinkles. The controller switches the LEDs ON/OFF and controls power to the mask. For MK-04, the cable for connecting with the controller is non-detachable, but the cable is detachable for MK-78. Model MK-04 contains many rose quartz crystals in inner surface for decoration purpose, the crystals do not contact with skin and there is no therapeutic effect.

Model MK66-H and EL00003 produce blue, red, and near infra-red (NIR) light in the visible spectrum (Blue: 415nm, Red: 630+/- 5nm, NIR: 830nm). 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 switches the LEDs ON/OFF, controls power to the mask, and switches treatment modes. The cable for connecting with the controller is detachable. Both MK66-H and EL00003 have two pieces of removable eye protection which are for protect eyes from the light.

6. Intended Use / Indications for Use

For MK-78, MK-04

The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the counter device that is intended for the use in the treatment of full-face wrinkles.

For MK66-H, EL00003

The LED Light Therapy Mask (Models: MK66-H, EL00003) 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 LED Light Therapy Mask (Models: MK66-H, EL00003) 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.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Company	Light Tree Ventures Europe B.V.	Harpar Grace International	ISMART Marketing Svcs Ltd	--
Trade Name	LED Light Therapy Mask	Shani Darden LED light therapy mask	FaceLITE	--
Classification Name	Light Based Over The Counter Wrinkle Reduction	Over-the-counter powered light based laser for acne	Light Based Over The Counter Wrinkle Reduction	--
510(k) Number	K221775	K214103	K191629	--
Product Code	OHS, OLP	OHS, OLP	OHS	Same
FDA Device Classification	Class II	Class II	Class II	Same
Use	Over the Counter	Over the counter	Over the counter	Same
Intended Use / Indications for Use	The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the counter device that is intended for the use in the treatment of full-face wrinkles. The LED Light Therapy Mask (Models: MK66-H, EL00003) 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	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	The faceLITE LED mask is an over the counter device that is intended for the use in the treatment of full-face wrinkles.	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	face. The LED Light Therapy Mask (Models: MK66-H, EL00003) 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.	spectrum and is intended for the use in the treatment of full-face wrinkles.		
Intended location of use	Face	Face	Face	Same
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelengths	1.MK-78, MK-04: Red: 630±5 nm NIR: 830nm 2.MK66-H, EL00003: Blue: 415nm, Red: 630nm +/- 5nm, NIR: 830nm	Blue: 415nm +/- 10nm, Red: 630nm +/- 10nm, NIR: 830nm +/-10nm.	Red: 630nm±10nm NIR: 830nm±10nm	Same
Total Intensity (mW/cm^2)	1.MK-78: 20-30 mw/cm^2 2.MK-04: 30mw/cm^2 3.MK66-H, EL00003: (1)Blue/Red 44 mw/cm^2 (2)Red/NIR 30 mw/cm^2	Blue/Red 44 mW/cm^2	30mw/cm^2 total	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
		Red/NIR 29 mW/cm^2		
Treatment Time	10 minutes	10 minutes	600 seconds	Same
Dose	1.MK-78: 12-18 J/cm^2 2.MK-04: 18 J/cm^2 3.MK66-H, EL00003: (1)Blue/Red: 26.4 J/cm^2 (2)Red/NIR: 18 J/cm^2	Blue 16.8 J/cm^2 Red 9.6 J/cm^2 Red 11 J/cm^2 NIR 7 J/cm^2	540 J/cm^2 (cumulative does)	Similar Note 2
Treatment protocol	Acne: 4 x weekly, 6 weeks; Wrinkles: 5 x weekly, 6 weeks	Acne: 4 x weekly, 6 weeks; Wrinkles: 5 x weekly, 6 weeks.	5 x weekly, 6 weeks	Same
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Yes	Same
Power supply	Rechargeable Lithium battery	100-240V	Rechargeable Lithium battery	Same

Comparison in Detail(s):

Note 1:

Though there is a minor difference of the “Total Intensity” between the subject and predicate devices, the device passed the testing according to IEC 60601-2-57, such a minor deviation would not affect safety and effectiveness.

Note 2:

The dose of the subject device is a single treatment dose calculated based on the total intensity, but the cumulative dose of MK-78, and MK-04 will be equal to the predicate device K191629. And the dose of

MK66-H and EL00003 will be almost the same as the predicate device K214103 when the dose of K214103 is calculated according to the total intensity. And the subject device passed the testing according to IEC60601-2-57, so such a minor deviation would not affect safety and effectiveness.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

The LED Light Therapy Mask (Model: MK-78, MK-04, MK66-H, EL00003) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device Description /Sample Size	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/ Significant Deviations	Test results
General requirements for basic safety and essential performance	The test sample is the final, finished product.	IEC 60601-1:2005/AMD 1:2012/AMD 2:2020	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product.	IEC 60601-1-2:2014+A1: 2020	No degradation of performance was found during test or Lower than limits of measurement	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	The test sample is the final, finished product.	IEC 60601-1-11:2015/AMD1:2020	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
Particular Requirements for The Basic Safety And Essential	The test sample is the final, finished product.	IEC 60601-2-57:2011	The test is carried out under the test method specified in the	NA	Pass

Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use			standard, and the test result is within the test acceptance range of the standard.		
Photobiological safety of lamps and lamp systems.	The test sample is the final, finished product.	IEC 62471:2006	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Shelf Life Test	The test sample is the final, finished product.	The Shelf Life Test Report performs the following tests on the product before and after accelerated aging, and after use: Performance test; Power Density Test; Leakage current test.	The device can meet the requirement of the performance test, Power Density test and Leakage current test.	NA	Pass

2) Biocompatibility testing

- 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

3) Usability Testing

Usability testing was conducted on the LED Light Therapy Mask (Model: MK-78, MK-04, MK66-H, EL00003), the device complies with IEC 62366-1 and IEC 60601-1-6.

4) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

8.2 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.

9. Final Conclusion：

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K191629 and K214103.