November 22, 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: K221946
Trade/Device Name: LED Light Therapy Mask (model: MK66R-B)
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: October 20, 2022
Received: October 20, 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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2022.11.22 11:42:54 -05'00'

For 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)*
K221946

Device Name
LED Light Therapy Mask (Model: MK66R-B)

Indications for Use *(Describe)*
The LED Light Therapy Mask (Model:MK66R-B) 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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510(k) Summary of K221946

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
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
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E-mail: regulation@kaiyanmedical.com

Manufacturer:

Manufacturer Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Contact Person (including title): Alain Dijkstra (CEO)
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E-mail: regulation@kaiyanmedical.com

Distributor:

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Application Correspondent:

Contact Person: Alain Dijkstra
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Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

Date of the summary prepared: November 20, 2022

2. Subject Device Information

Classification Name: Light based over the counter wrinkle reduction
Trade Name: LED LIGHT THERAPY MASK
Model Name: MK66R-B
Trademark: CurrentBody Skin™
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CRF 878.4810
Regulatory Class: II

3. Predicate Device 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: 21 CRF 878.4810
Regulation Class: II

4. 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.

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 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 controller switches the LEDs ON/OFF and controls power to the mask. The device does not have an adapter, please use adapters of the following specifications: input: 100-240Va.c., 50Hz/60Hz, output: DC 5V, 2A.

The device produces 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. And the cable for connecting with the controller is non-detachable.

5. Intended Use / Indications for Use

The LED LIGHT THERAPY MASK (Model:MK66R-B) is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.

6. Comparison to predicate device

Compare with predicate devices, 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	Remark
Company	Light Tree Ventures Europe B.V.	ISMART Marketing Svcs Ltd	--
Trade Name	LED LIGHT THERAPY MASK	FaceLITE	--
Classification Name	Light Based Over The Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction	--
510(k) Number	K221946	K191629	--
Product Code	OHS	OHS	Same
FDA Device Classification	Class II	Class II	Same
Use	Over the Counter	Over the counter	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
Intended Use / Indications for Use	The LED LIGHT THERAPY MASK (MK66R-B) is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	The faceLITE LED mask is an over-the-counter device that is intended for the use in the treatment of full-face wrinkles.	Same
Intended location of use	Face	Face	Same
Energy Type	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Red: 630±5 nm NIR: 830nm	Red: 630nm±10nm NIR: 830nm±10nm	Same
Total Intensity (mW/cm^2)	30mw/cm^2	30mw/cm^2 total	Same
LED number	630±5nm: 66 830nm: 66	630±5nm: 49 830nm: 49	Different, Note
LED distribution	Uniform distribution	Uniform distribution	Same
Power flux (mW/cm^2)	630±5nm:15-20 mW/cm^2 830nm:10-15 mW/cm^2	630±5nm: 15-20 mW/cm^2 830nm: 6-12 mW/cm^2	Similar Note
Treatment Time	10 minutes	600 seconds	Same
Dose	540 J/cm2 (cumulative does)	540 J/cm2 (cumulative does)	Same
Treatment protocol	5 x weekly, 6 weeks	5 x weekly, 6 weeks	Same
Software controller	Device uses a timer and software to control treatment duration	Yes	Same
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Same

Comparison in Detail(s):

Note: Although the “LED number” and “Power flux” is a little different from the predicate devices, both of them have the same out wavelengths, total Intensity, treatment time and dose, and they all complied with the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 and IEC 62471 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Summary of Non-Clinical Performance Testing

LED LIGHT THERAPY MASK (Model: MK66R-B) 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	The test sample is the final, finished product of	IEC 60601-1:2005+A1:2012+A2:2020 Edition: 3.2 2020-08	The test is carried out under the test method specified in the standard, and the test	NA	Pass

essential performance Location: VOL_010_A8. Electrical Safety and EMC_ 001_A8-1. IEC 60601-1, IEC 60601-1-11 Test Report	representative model: MK66R-B		result is within the test acceptance range of the standard.		
Electromagnetic disturbances Location: VOL_010_A8. Electrical Safety and EMC_ 004_A8-4. IEC 60601-1-2 Test Report	The test sample is the final, finished product of representative model: MK66R-B	IEC 60601-1-2:2014+A1:2020 Edition: 4.0 2020-09	No degradation of performance was found during test or Lower than limits of measurement.	NA	Pass
Basic safety and performance requirements for home healthcare environment Location: VOL_010_A8. Electrical Safety and EMC_ 001_A8-1. IEC 60601-1, IEC 60601-1-11 Test Report	The test sample is the final, finished product of representative model: MK66R-B	IEC 60601-1-11:2015+A1:2020 Edition: 2.0 2020-07	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
Particular requirements for the basic safety and essential performance of non-laser	The test sample is the final, finished product of representative model: MK66R-B	IEC 60601-2-57 Edition 1.0 2011-01	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

light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use Location: VOL_010_A8. Electrical Safety and EMC_ 002_A8-2. IEC 60601-2-57 Test Report					
Photobiological safety of lamps and lamp systems Location: VOL_010_A8. Electrical Safety and EMC_ 003_A8-3. IEC 62471 Test Report	The test sample is the final, finished product of representative model: MK66R-B	IEC 62471 First edition 2006-07	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
Usability Study Location: VOL_009_A7. Usability	The test sample is the final, finished product of representative model: MK66R-B	IEC 62366-1 Edition 1.0 2015-02 and IEC 60601-1-6 Edition 3.1 2013-10	The subject device can meet the usability goal of IEC 62366-1 and IEC 60601-1-6 standards.	NA	Pass
Shelf Life Test	The test sample is the final, finished product of representative model: MK66R-B	The Shelf Life Test Report performs the following tests on the product before and after accelerated aging, and after use: Performance test; Key life test; Mask bending test; Plug and pull test;	Performance Test: ● Appearance: ● The device should be no deformation, the surface is smooth and free of burrs, no color sports. ● The silicone	NA	Pass

		Plug and pull test; Power Density Test; Leakage current test;	thickness is 9.42 ± 0.1 mm on point A, 5 ± 0.1 mm on point B. Key life test: ● There should be no key stuck. ● The key is sensitive. ● The device can be turned on and off normally. ● The LED indicator can work normally when pressing the key. Mask bending test: ● The device should be no cracks, no damage, can be charged and work normally. Plug and pull test: ● The device can be charged and work normally: The indicator can light up normally when plug the adapter into the power outlet. Power Density Test: ● Power Density: 30 mw/cm2 ± 10% (27 - 33 mw/cm2); Leakage current test: ● Should meet the clause 8.7.4 of IEC 60601-1 required.		

1) Biocompatibility statement

The component materials for Velcro Straps of the LED LIGHT THERAPY MASK (Models: MK66R-B) is identical to the corresponding component for Velcro Straps of the Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B) in formulation, processing,

sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents), that manufactured by SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD and has been clarified in K202390 on July 14, 2021.

The patient contacting material silicone of the outer surface and inner surface of model MK66R-B is identical to the materials for Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-66USBA, MK-66USBB, MK-02O, MK-02A, MK-02B) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents), that manufactured by SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD and has been clarified in K202390 on July 14, 2021.

2) Usability Testing

Usability testing was conducted on the LED LIGHT THERAPY MASK (Model: MK66R-B), which complies with IEC 62366-1 and IEC 60601-1-6.

3) 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.

7.2 Summary of 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.

8. Final Conclusion:

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