June 25, 2025

Shenzhen Kaiyan Medical Equipment Co., Ltd
Dijkstra Alain
CEO
Building#3 and Building#5, 40th of Fuxin Street,
Huaide Community Fuyong Town
Shenzhen, Guangdong 518103
China

Re: K250966
Trade/Device Name: CurrentBody Skin™ LED Light Therapy Mask Series 2 (MK-90H)
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: March 31, 2025
Received: March 31, 2025

Dear Dijkstra Alain:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.06.25 19:56:38 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250966

Device Name
CurrentBody Skin™ LED Light Therapy Mask Series 2 (Model: MK-90H)

Indications for Use *(Describe)*
The CurrentBody Skin™ LED Light Therapy Mask Series 2 (Model: MK-90H) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K250966

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: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
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Fax: +86-755-25024651
E-mail: alaindijkstra@kaiyanmedical.com

Distributor:

Company: CurrentBody.Com Ltd
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Application Correspondent:

Contact Person: Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Tel: +86 755 82129361
Fax: +86 755 25024651
Email: registrar01@kaiyanmedical.com

2. Subject Device Information:

Trade Name: CurrentBody Skin™ LED Light Therapy Mask Series 2, Model: MK-90H
Classification Name: Light Based Over the Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS

Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device (K221946)

Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED LIGHT THERAPY MASK
Classification Name: Light Based Over the Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

The CurrentBody Skin™ LED Light Therapy Mask Series 2 (Model: MK-90H) is a home use wearable LED phototherapy device whose purpose is to produce an even, cool, narrow band of light for aesthetic indication for treating facial wrinkles. It emits light energy in the red and near infrared (NIR) region of the light spectrum.

The device consists of a flexible silicone mask that contains light emitting diodes (LEDs) and a controller, multi-straps, a USB-C charging cord, a pair of eye inserts and a storage bag. The LEDs generate the light. The mask is worn on the face and is held in place by the adjustable strap. The controller contains a rechargeable Lithium ion polymer battery and controls power to the mask. The controller has only one key to switch the LEDs ON/OFF and it will automatically shut down after a 10-minute treatment is completed.

5. Intended Use / Indications for Use

The CurrentBody Skin™ LED Light Therapy Mask Series 2 (Model: MK-90H) 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 the predicate device, the subject device is very similar in design principle, intended use, indications for use, functions and the applicable standards. The differences

between the subject device and predicate device do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device (K221946)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	--
510 (K) Number	K250966	K221946	--
Device Name	CurrentBody Skin™ LED Light Therapy Mask Series 2	LED LIGHT THERAPY MASK	--
Model	MK-90H	MK66R-B	--
OTC/Rx	OTC	OTC	Same
Device Classification	Class II	Class II	Same
Product Code	OHS	OHS	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use / Intended use	The CurrentBody Skin™ LED Light Therapy Mask Series 2 (Model: MK-90H) is an over-the- counter device that is intended for the use in the treatment of full-face wrinkles.	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.	Same
Intended Area of Use	Face	Face	Same
Power Source	Rechargeable Lithium battery: 3.7V, 2600mAh, 9.62Wh	Rechargeable Lithium battery	Same (Note 1)
Energy Type	Light emitting diodes	Light emitting diodes	Same
Type	Mask	Mask	Same
Dose/per time(J/cm^2)	18	18	Same
LED Wavelength	Red: 633nm Infrared: 830nm	Red:630±5nm NIR:830nm	Similar (Note 2)

Elements of Comparison	Subject Device	Predicate Device (K221946)	Remark
LED Number	633nm:110 830nm:110	630±5nm:66 830nm:66	Different (Note 2)
Total Intensity (mW/cm^2)	30 mW/cm²	30 mW/cm²	Same
Treatment Time	10 minutes per treatment 5 times weekly for 6 weeks	10 minutes per treatment 5 x weekly, 6weeks	Same
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Same
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC 62471	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO10993-23	ISO 10993-1 ISO10993-5 ISO10993-10 ISO10993-23	Same

Comparison in Detail(s):

Note 1:

The power supply for the subject device is the same as that of the predicate device and the lithium battery of the subject device has been tested under standard IEC 62133-2.

Note 2:

The wavelengths of subject device (633nm and 830nm) are slightly different, but are within the wavelength tolerance of the predicate devices (630nm±5nm, 830nm). The LED number of subject device is a little different from that of the predicate device, but the wavelengths, total intensity, treatment time and dose are the same for both and comply with the requirements of

IEC60601-1, IEC60601-1-2, IEC60601-2-57 and IEC62471 safety standards. Therefore, these minor differences do not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical Safety, and Electromagnetic Compatibility Test

Non-clinical testing was performed on the subject device to validate the design and ensure compliance with the following standards related to medical device electrical safety, electromagnetic compatibility, photobiological safety and battery safety:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment --Part 1: 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 Edition 2.0 2023 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2:2017+AMD1:2021 Edition1.1 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.

2) **Biocompatibility Test**

The component materials (mask inner shell and outer shell) of the subject device are identical in formulation, processing and sterilization to the corresponding component materials (mask inner shell and outer shell) of the previously cleared devices (K221444, LED Eye Perfector, Model:

EY-36A) and no other chemicals added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). The eye protections of the subject device are identical in formulation, processing, sterilization, and geometry to the eye protection of the previously cleared device (K242593, CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask, model: MK-90C) and no other chemicals added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). Also there is no change in biocompatibility since the previously cleared devices. Therefore, based on this information, the subject device can comply with the biocompatibility requirements of 1S0 10993-5 (cytotoxicity), ISO 10993-10 (sensitization) and ISO 10993-23 (irritation).

3) Software Verification and Validation

Software verification and validation testing was performed and documentation provided in accordance with the recommendations of the Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

7.2 Summary of Clinical Performance

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

8. Date of the summary prepared: June 23, 2025

9. Final Conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed predicate device K221946.