February 14, 2025

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

Re: K242593
Trade/Device Name: CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)
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: January 17, 2025
Received: January 17, 2025

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 (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: 2025.02.14 16:11:56 -05'00'

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.

Submission Number *(if known)*

K242593

Device Name

CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)

Indications for Use *(Describe)*

For MK-90C:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90C) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris of the face and use in the treatment of full-face wrinkles.
For MK-90M:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90M) is an over the counter device intended for the use in the treatment of full face wrinkles.
For MK66RB-F:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK66RB-F) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris.
For MK-90N:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90N) is an over the counter device, is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital 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.

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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 of K242593

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
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Contact Person (including title): Alain Dijkstra (Manager)
Tel: +86-135-10378748
Fax: +86-755-25024651
E-mail: registrar01@kaiyanmedical.com

Application Correspondent

Contact Person (including title): Alain Dijkstra (Manager)
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Shenzhen, Guangdong 518103, China Shenzhen Guangdong 518103 China
Tel: +86-135-10378748
Fax: +86-755-25024651
Email: registrar01@kaiyanmedical.com

Distributor:

Company: CurrentBody.Com Ltd
Address: Q17, Crossley Road, Stockport, Greater Manchester, SK4 5BB United Kingdom

2.Subject Device Information:

Device Name:

Device Trade Name: CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (MK-90C, MK-90M, MK66RB-F, MK-90N)

Common Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name: Light Based Over The Counter Wrinkle Reduction

Regulation Number: 21 CFR 878.4810

Product Code(s): OHS, OLP

Device Description Summary

The CurentBody™LED 4 in 1 Zone Facial Mapping 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 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 CurentBody™LED 4 in 1 Zone Facial Mapping Mask has 4 models, MK-90C, MK-90M, MK66RB-F and MK-90N.The controller contains a rechargeable lithium battery. The user charges the controller by connecting the charging cable with an adapter (AC100-240V, 50Hz/60Hz 5V 2A).The LED Light Therapy Mask cannot be operated while charging.

Intended Use/ Indications for Use:

For MK-90C:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: Mk-90C) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris of the face and use in the treatment of full-face wrinkles
For MK-90M:
The CurrentBody™ LED 4in 1 Zone Facial Mapping Mask(Models: MK-90M is an over the counter device intended for the use in the treatment of full face wrinkles.
For MK66RB-F:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK66RB-F) is an over the counter device, specifically indicated to treat mild to moderate acne vulgaris.
For MK-90N:
The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(Models: MK-90N) is an over the counter device, is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles.

3.Legally Marketed Predicate Devices:

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214103	Shani Darden LED light therapy mask	OLP, OHS
K240089	Face Patches (MT-12MA, MT-12MC)	OHS, OLP, GEX

4.General Comparison:

Item	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(K242593)	**Shani Darden LED light therapy mask (K214103)**	**Face Patches (MT-12MA, MT-12MC) (K240089)**	
Product Code	OHS, OLP	OLP, OHS	OHS, OLP, GEX	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
FDA Device Classification	Class II	Class II	Class II	Same
Use	Over The Counter	Over The Counter	Over The Counter	Same

Item	Subject Device CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(K242593)	Predicate Device 1 Shani Darden LED light therapy mask (K214103)	Predicate Device 2 Face Patches (MT-12MA, MT-12MC) (K240089)	Remark
Indications for Use	For MK-90C: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90C) is an over the counter device, specifically indicated to treat **mild to moderate acne vulgaris of the face** and use in the treatment of **full-face wrinkles.** For MK-90M: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90M) is an over the counter device intended for the use in the treatment of **full face wrinkles.** For MK66RB-F: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK66RB-F) is an over the counter device, specifically indicated to treat **mild to moderate acne vulgaris.** For MK-90N: The CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (Models: MK-90N) is an over the counter device, is generally indicated to treat **dermatological conditions** and specifically indicated for treatment of **periorbital wrinkles.**	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**.	Face Patches (Model: MT-12MA) is an Over-the-Counter (OTC) device intended for treatment of **mild to moderate inflammatory acne**. Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of **mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles)**.	Similar Note 1
Intended location of use	Face	Face	Face	Same

Performance Comparison:

Item	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(K242593)	**Shani Darden LED light therapy mask (K214103)**	**Face Patches (MT-12MA, MT-12MC) (K240089)**	
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelengths	**MK-90C** Mode 1: Red + Infrared (633nm+830nm) Mode 2: Blue + Red (415nm+633nm) Mode 3: Yellow + Infrared (590nm+830nm) **MK-90M** Mode: Red + Infrared (633nm+830nm) **MK66RB-F** Mode: Red + Blue (633nm +415nm) **MK-90N** Mode: Yellow + Infrared (590nm+830nm)	Blue: 415nm +/- 10nm Red: 630nm +/- 10nm NIR 830nm +/-10nm	MT-12MA: 415 ± 10nm and 630 ± 10nm; MT-12MC has 3 modes: Mode 1: 630 ± 10nm and 415 ± 10nm, Mode 2: 630 ± 10nm and 830nm ± 10nm, Mode 3: 590nm ± 10nm	Similar Note 2
Power Density	415nm: 25±5mW/cm^2; 633nm: 20±5mW/cm^2; 590nm: 15±5mW/cm^2; 830nm: 10±5mW/cm^2	Blue: 28 mW/cm^2 Red: 16 mW/cm^2 and Red: 18 mW/cm^2 NIR: 11 mW/cm^2	For MT-12MA: 630nm: 5 mW/cm^2 415nm: 25 mW/cm^2 630+415nm: 30 mW/cm^2 For MT-12MC: 630nm (type 1): 5 mW/cm^2 415nm: 25 mW/cm^2 Mode 1 - total: 30 mW/cm^2 830nm: 15 mW/cm^2 630nm (type 2): 20 mW/cm^2 Mode 2 - total: 35 mW/cm^2 Mode 3 - 590nm: 35 mW/cm^2	Different Note 3
LED distribution	Uniform distribution	Uniform distribution	Uniform distribution	Same
Treatment Time	10 minutes	10 minutes	For MT-12MA(630+415nm): 3 minutes per treatment For MT-12MCN(mode 1 - 630+415nm): 3 minutes per treatment For MT-12MC (mode 2 - 630+830nm): 9 minutes per treatment For MT-12MC (mode 3 - 590nm): 21 minutes per treatment	Same

Item	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask(K242593)	**Shani Darden LED light therapy mask (K214103)**	**Face Patches (MT-12MA, MT-12MC) (K240089)**	
Treatment protocol	Wrinkles: 5 x weekly, 6 weeks Acne: 4 x weekly, 6 weeks	Wrinkles: 5 x weekly, 6 weeks Acne: 4 x weekly, 6 weeks	NA	Same
Software Controlled	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	User interface software allows the operator to access and control all device functions.	Same
Power supply	MK-90C and MK-90N: 3.7Vdc, 5200mAh，19.24Wh Lithium battery MK66RB-F and MK-90M: 3.7Vdc, 2600mAh，9.62Wh Lithium battery	100-240V	Controller: 3.6V, 65mAh lithium battery, 0.234Wh	Different Note 4
Power input/output	Adapter Input: 100-240Vac,50-60Hz Output: DC 5V,2A	Electrical Input to power adaptor: 100v-240v. 50/60Hz. Rated at 0.7A. Electrical Output from power adaptor: 12V, 1A	NA	Same

Safety Comparison:

Item	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	CurrentBody™ LED 4 in 1 Zone Facial Mapping Mask (K242593)	**Shani Darden LED light therapy mask (K214103)**	**Face Patches (MT-12MA, MT-12MC) (K240089)**	
Biocompatibility				
Cytotoxicity Irritation	No Cytotoxicity Irritation	No Cytotoxicity Irritation	No Cytotoxicity Irritation	Same
Skin sensitization	No evidence of skin sensitization	No evidence of skin sensitization	No evidence of skin sensitization	
Irritation	No irritation	NA	No irritation	
EMC, Electrical Safety				
Electrical safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Home Use	Comply with IEC 60601-11	Comply with IEC 60601-11	The proposed device is Prescription Use and operated by professional personnel, so it does not need to be tested by IEC 60601-1-11	Same

Particular Requirements	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57	Same
Photobiological safety	Comply with IEC 62471	Comply with IEC 62471	Comply with IEC 62471	Same

Difference Analysis

Note 1: Although the "Indications for Use / Intended use" is a little different from the predicate devices, the acne treat function of the model MK-90C(mode 2) and MK66RB-F of subject device is consistent with predicate device 2 (Model: MT-12MA, K240089), the wrinkle removal function of the model MK-90C (mode 1,3), MK-90M and MK-90N of subject device is consistent with predicate device 1 (K214103) and predicate device 2 (Model: MT-12MC, K240089). So, this difference will not affect the safety and effectiveness of the subject device.

Note 2: The light wavelength is very similar but not identical. The proposed device emits blue light, red light, yellow light and IR light.

The variance range of each wavelength of the predicate devices is ±10nm, which can cover the wavelength of the proposed device. This represents a minor difference and not one to affect equivalence. The device has passed testing according to IEC 60601-2-57. Therefore, there is no effect on safety, effectiveness, or intended use of the proposed device.

The wavelengths of the subject device can be covered by the predicate devices. The MK-90C Mode 1 and MK-90M are both the combination of 633nm and 830nm. They are consistent with the model MT-12MC, mode 2 of the predicate device 2 (K240089, 630 ± 10nm and 830nm ± 10nm).

The wavelengths of MK-90C Mode 2 and MK66RB-F are both the combination of 633nm and 415nm, which are consistent with the model MT-12MA of predicate device 2 (K240089, 415 ± 10nm and 630 ± 10nm)

The wavelengths of MK-90C Mode 3 and MK-90N are both the combination of 590nm and 830nm, the yellow light can be consistent with the model MT-12MC, mode 3 of predicate device 3 (K240089).

So, the treatment wavelength of the subject device is acceptable.

Note 3: The proposed device has similar effective irradiance with the primary predicate device (K240089) in Red, Blue, Infrared, Yellow light source and also similar in combination of Red and Infrared type and combination of Blue and Red type. For the combination of Yellow and infrared type, the proposed device is different with predicate device (K240089).

From the comparison above, the power density of the combination of Yellow and infrared type is 15+10=25mW/cm^2, while mode 3 of Model MT-12MC of predicate device (K240089) is 35 mW/cm^2, we can see the proposed devices' effective irradiance is less than secondary predicate's, so it means the proposed device will not raise safety concerns in this particular difference.

Note 4: The proposed device and predicted devices are all powered by rechargeable Lithium battery. The battery in the proposed device supports a longer battery life as well as fast charging. This does not affect the safety, effectiveness, or indications for use of the proposed device.

Comparison conclusion

The proposed device and predicate devices have the same product code, regulation number, indications for use. There are a little differences in wavelength, power density and power input / output. But these differences will not result in differences on safety and performance between

purposed device and the predicated device.

5.Test Summary

5.1Non-Clinical Test

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC60601-1:2005+AMD1: 2012+AMD2: 2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility-Requirements and tests.

IEC TR 60601-4-2:2016, Medical electrical equipment- Part 4-2: Guidance and interpretation -Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

IEC 60601-1-11:2015+AMD1:2020, 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 60601-2-57:2023,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 62471: 2006 Photobiological safety of lamps and lamp system.

5.2Biocompatibility Test:

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), ISO 10993-23 (Skin Irritation).

5.3 Light output

The Light output test validated that the output of light from the devices are the same as stated in the specifications.

5.4 Software verification and validation

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 basic 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.

5.5 Clinical Test

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..

6. Date of the summary prepared: February 12, 2025

7. Final Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K214103 and K240089.