September 27, 2024

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

Re: K241933
Trade/Device Name: HIGHERDOSE Red and Infrared Light Mask (MK66-L)
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: June 12, 2024
Received: July 2, 2024

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: 2024.09.27 23:22:48 -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.

Submission Number *(if known)*

K241933

Device Name

HIGHERDOSE RED AND INFRARED LIGHT MASK (MK66-L)

Indications for Use *(Describe)*

The HIGHERDOSE Red And Infrared Light Mask (Model: MK66-L) 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K241933

510(k) Summary

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
Tel: +86 755 82129361
Fax: +86 755 25024651
E-mail: alaindijkstra@kaiyanmedical.com

Distributor

Company Name: HIGHERDOSE LLC
Address: 42 Broadway, 12th Floor, #212, NewYork, NY 10004
Establishment Registration Number: 3019734322
Contact Person: Sumish Khadka
E-mail: sumish@higherdose.com

Manufacturer:

Manufacturer Name: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
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
Tel: +86 755 82129361
Fax: +86 755 25024651
E-mail: alaindijkstra@kaiyanmedical.com

Application Correspondent:

Contact Person: Alain Dijkstra
Company: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
Address: Building #3, and Building#5 40th of Fuxin street, Huaide Community, Fuyong Town, Baoan District, Shenzhen, Guangdong, 518103, China
Tel: +86 755 82129361

Fax: +86 755 25024651
E-mail: regulation@kaiyanmedical.com

2. Date of the summary prepared: September 26, 2024

3.Subject Device Information

Classification Name: Light Based Over-The Counter Wrinkle Reduction (OHS)
Trade Name: HIGHERDOSE Red And Infrared Light Mask
Model Name: MK66-L
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 878.4810
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Light Tree Ventures Europe B.V
Trade Name: LED Light Therapy Mask
Classification Name: Light based over the counter wrinkle reduction
510(K) Number: K221775
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulation Class: II

Predicate Device 2 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 3 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

Predicate Device 4 Information
Sponsor: SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD
Trade Name: Aduro Light Beauty Mask
Classification Name: Light based over the counter wrinkle reduction
510(K) Number: K202390
Review Panel: General & Plastic Surgery
Product Code: OHS,OLP
Regulation Number: 878.4810
Regulation Class: II

5. Device Description

The HigherDose Red and Infrared Light Mask is a home wearable light-emitting diode phototherapy device with two proven wavelengths of light 630nm and 830nm(near infrared light) for treatment of full-face wrinkles,

The face mask combine Red (630nm)and near infrared light (830nm).Harnessed at the perfect measurement to rejuvenate the skin, these two wavelengths work below the skin's surface to stimulate the natural rejuvenation process ,creating a complexion that is visibly growing and noticeably healthier looking.

The mask is worn on the face and is held in place by head 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 HIGHERDOSE Red And Infrared Light 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.

6. Intended Use / Indications for Use

For MK-66L

The HIGHERDOSE Red And Infrared Light Mask (Model: MK66-L) is an over the counter device that 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	Predicate Device 3	Predicate Device 4	Remark
Company	HigherDOSE LLC	Light Tree Ventures Europe B.V.	Harpar Grace International	ISMART Marketing Svcs Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	--
Trade Name	HigherDose Light Face Mask	LED Light Therapy Mask	Shani Darden LED light therapy mask	FaceLITE	Aduro Light Beauty Mask	--
Classification Name	Light Based Over The Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction	Over-the-counter powered light based laser for acne	Light Based Over The Counter Wrinkle Reduction	Light Based Over-The-Counter Wrinkle Reduction	--
510(k) Number	TBD	K221775	K214103	K191629	K202390	--
Product Code	OHS	OHS, OLP	OHS, OLP	OHS	OHS,OLP	Same
FDA Device Classification	Class II	Class II	Class II	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Over the counter	Over the counter	Over the counter	Same
Intended Use / Indications for Use	The HIGHERDOSE Red And Infrared Light Mask (Model: MK66-L) is an over the	The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the	The Shani Darden LED light therapy mask is an over-the-counter	The faceLITE LED mask is an over the counter device that is intended for	The Aduro Light Beauty Mask (Model: MK-66O, MK-66USBO, MK-02O) emits energy in the red and blue region of the spectrum, specifically	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
	counter device that is intended for the use in the treatment of full-face wrinkles.	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 face. The LED Light Therapy Mask (Models: MK66-H,	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.	the use in the treatment of full-face wrinkles.	indicated to treat full face wrinkles and/or mild to moderate acne.	

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
		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.				
Intended location of use	Face	Face	Face	Face	Face	same
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Red: 630nm±10nm NIR: 830nm±10nm	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	Red:640nm±10nm Blue:465nm±10nm	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
Total Intensity (mW/cm^2)	Red 20mw/cm^2 , Infrared Red : 30mw/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 Red/NIR 29 mW/cm^2	30mw/cm^2 total	30mw/cm^2	same
Treatment Time	10 minutes	10 minutes	10 minutes	600 seconds	10 minutes/day	Same
Dose	Red 12, Infrared Red: 18 J/cm^2	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)		Same
Treatment protocol	3-5 times /week	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	3 times per week	Same
Software controller	Device uses a timer and software	Device uses a timer and	Device uses a timer and	Yes	Device uses a timer and software	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
	to control treatment duration	software to control treatment duration	software to control treatment duration		to control treatment duration	
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	100-240V	Rechargeable Lithium battery	Rechargeable Lithium battery	Same

Final Conclusion:
The subject device is the same or similar to the legally marketed predicate device K221775, K214103, K191629 and K202390.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary
The HIGHERDOSE Red And Infrared Light Mask (Model: MK-66L) 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	The test sample is the final,	IEC 60601-1-11:2015/AM	The device operates normally, and	NA	Pass

equipment and medical electrical systems used in the home healthcare environment.	finished product.	D1:2020	can provide basic safety and essential performance.		
Particular Requirements for The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use	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 standard, and the test result is within the test acceptance range of the standard.	NA	Pass
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

The component materials of the subject device are identical to the corresponding component materials of the previously cleared devices (K202390) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

Here 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 ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-10 (Irritation).

3) Usability Testing

Usability testing was conducted on the HIGHERDOSE Red And Infrared Light Mask, 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 K221775, K214103, K191629 and K202390.