September 4, 2025

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Alain Dijkstra
Submission Correspondence
Building #3 and building #5, No.40 of Fuxin Street, Huaide
Community, Fuyong Town, Baoan District
Shenzhen, Guangzhou 518103
China

Re: K251781
Trade/Device Name: Kala Mini 2.0 (kala-04)
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, ILY
Dated: June 10, 2025
Received: June 11, 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: 2025.09.04 23:25:57 -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)*
K251781

Device Name
KALA MINI 2.0 (KALA-04)

Indications for Use *(Describe)*
KALA MINI 2.0 (Model: KALA-04) (Mode 1) is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

KALA MINI 2.0 (Model: KALA-04) (Mode 2) is an over-the counter device intended for 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.

K251781 - 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

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 (CEO)

Tel: 0755-82129361

Fax: 0755-25024651

E-mail: alaindijkstra@kaiyanmedical.com

Distributor

Distributor Name: Kala Therapy Inc

Address: 1100 Courtneypark Dr. E. Mississauga, ON L5T 1S7, Canada

Contact Person: Cam Stajer

E-mail: cam@kalaredlight.com

Manufacturer:

Manufacturer 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 (CEO)

Tel: 0755-82129361

Fax: 0755-25024651

E-mail: alaindijkstra@kaiyanmedical.com

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: registrar@kaiyanmedical.com

2. Date of the summary prepared: August 9, 2025

3. Subject Device Information

Classification Name: Light Based Over-the-Counter Wrinkle Reduction (OHS)

Trade Name: KALA MINI 2.0

Model Name: KALA-04

Review Panel: General & Plastic Surgery

Product Code: OHS

Subsequent Product Codes: ILY

Regulation Number: 878.4810

Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Shenzhen Nuon Medical Equipment Co., Ltd

Trade Name: Radiant Renewal Skincare Wand (Models: HD-44,HD-44A,HD-44B,HD-44C,HD-69,HD-69A,HD-69B)

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

510(K) Number: K242151

Review Panel: General & Plastic Surgery

Product Code: OHS, OLP

Regulation Number: 878.4810

Regulation Class: II

Predicate Device 2 Information

Sponsor: Biophotas Inc

Trade Name: BIOPHOTAS Celluma CONTOUR

Classification Name: Light Based Over The Counter Wrinkle Reduction, Lamp, Infrared, Therapeutic Heating and Fat Reducing Low Level Laser

510(K) Number: K232977

Review Panel: General & Plastic Surgery

Product Code: OHS, OLI, ILY

Regulation Number: 878.4810

Regulation Class: II

Predicate Device 3 Information

Sponsor: H.V.R., INC.

Trade Name: HVR PAIN RELIEF DEVICE

Classification Name: Lamp, Infrared, Therapeutic Heating

510(K) Number: K101716

Review Panel: Physical Medicine

Product Code: ILY

Regulation Number: 890.5500
Regulation Class: II

5. Device Description

The KALA MINI 2.0 (Model: KALA-04) is a home use light-emitting diode phototherapy device with four proven wavelengths of red light: 630nm, 660nm, and near infrared red light: 830nm, 850nm, the red light (630nm, 660nm) are known to treat the wrinkles and the NIR light (830nm, 850nm) to provide topical heating to elevate tissue temperature for the temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain or muscle spasms and to provide a temporary increase in local blood circulation.

The equipment is a panel that contains LEDs. There are two buttons, one LED display screen on this panel: the button used to control the treatment time and the irradiance of the device; the LED display screen will show the remaining treatment time. Beside the buttons, there are power indicator which will indicate the remaining battery power.

There are fixed straps on the back of the panel, which you can use to hold the panel in your hand. The surfaces patients will contact with hand are constructed of silicone.

The controller contains a rechargeable Lithium battery, the power supply (adaptor) is used to charge the Lithium battery and be connected to a suitable mains outlet via a 2 or 3 pin input socket and wall plug. The KALA MINI 2.0 (Model: KALA-04) cannot be operated while charging. The cable for connecting with the controller is detachable.

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

KALA MINI 2.0 (Model: KALA-04) (Mode 1) is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

KALA MINI 2.0 (Model: KALA-04) (Mode 2) is an over-the counter device intended for 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 K242151**	**Predicate Device 2 K232977**	**Predicate Device 3 K101716**	**Remark**
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Nuon Medical Equipment Co., Ltd	Biophotas Inc	H.V.R., INC.	--
Trade Name	KALA MINI 2.0	Radiant Renewal Skincare Wand	BIOPHOTAS Celluma CONTOUR	HVR PAIN RELIEF DEVICE	--
Classification Name	Light Based Over the Counter Wrinkle Reduction and	Light Based Over the Counter Wrinkle Reduction, Over-The-Counter Powered Light-Based Laser for Acne	Light Based Over the Counter Wrinkle Reduction, Lamp, Infrared, Therapeutic Heating and Fat Reducing Low Level Laser	Lamp, Infrared, Therapeutic Heating	--
510(k) Number	TBD	K242151	K232977	K101716	--
Product Code	OHS, ILY	OHS, OLP	OHS, OLI, ILY	ILY	Same
FDA Device Classification	Class II	Class II	Class II	Class II	Same
Intended Use / Indications for Use	KALA MINI 2.0 (Model: KALA-04) (Mode 1) is intended to provide topical heating for the purpose of	The Radiant Renewal Skincare Wand (Models: HD-44, HD-44A, HD-44B, HD-69, HD-69A) is an over-	The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic	The HVR Lamp is an over-the counter handheld device used for the treatment of chronic pain by emitting	Same

Elements of Comparison	Subject Device	Predicate Device 1 K242151	Predicate Device 2 K232977	Predicate Device 3 K101716	Remark
	elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. KALA MINI 2.0 (Model: KALA-04) (Mode 2) is an over-the counter device intended for the treatment of full-face wrinkles.	the counter device intended for the treatment of full-face wrinkles. The Radiant Renewal Skincare Wand (Models: HD-44C, HD-69B) is an over-the-counter device intended for the treatment of the mild to moderate inflammatory acne.	treatment for the reduction of circumference of hips, waist, and thighs. The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis, and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The BioPhotas Celluma CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	energy in the near-infrared spectrum for the temporary relief of minor aches and pains in muscles and joints, arthritis and muscle spasms, relieving stiffness, promoting relaxation of muscle tissue and to temporarily increase local blood circulation where applied.	

Elements of Comparison	Subject Device	Predicate Device 1 K242151	Predicate Device 2 K232977	Predicate Device 3 K101716	Remark
Intended location of use	Face and body	Face	Face and body	body	same
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Mode 1: Red+NIR 660nm±10nm+850nm±10nm Mode 2: Red+NIR 630nm±10nm+830nm±10nm	HD-44: Red+IR 630±10nm & 830±10nm HD-44A/HD-69A: Red 630±10nm HD-44B/HD-69: Yellow 590±10nm HD-44C/HD-69B: Blue 415±10nm;	Red: 640nm+/-25nm (615-665nm) 880nm +/50nm (830nm – 930nm)	650nm to 950nm	Similar Note 1
Total Intensity (mW/cm^2)	**Mode 1** High brightness mode: 660nm±10nm: 50±10mW/cm^2 850nm±10nm: 50±10mW/cm^2 Total: 100±10mW/cm^2 Bedtime mode: 7±10mW/cm^2 **Mode 2** High brightness mode: 630nm: 45±10mW/cm^2 830nm: 45±10mW/cm^2 Total: 90±10mW/cm^2 Bedtime mode: 7±10mW/cm^2	**HD-44:** Red+IR 630±10nm: 20~50 830±10nm: 25~55 Total:45~105 **HD-44A&HD-69A:** Red 630±10nm: 30~50 **HD-44B/HD-69:** Yellow 590±10nm: 10~30 **HD-44C/HD-69B**: Blue 415±10nm: 35~50	640nm - 4.2mW/cm^2 880nm - 0.7mW/cm^2	50-80 mW/cm^2	Similar Note 2
Treatment Time	5 mins, 10 mins, 15 mins and 20 minutes(optional)	5 minutes per treatment	30 minutes	90 seconds	Same
Software	Device uses a timer and	Device uses a timer and	Device uses a timer and	Unknown	Same

Elements of Comparison	Subject Device	Predicate Device 1 K242151	Predicate Device 2 K232977	Predicate Device 3 K101716	Remark
controller	software to control treatment duration and LED's intensity	software to control treatment duration	software to control treatment duration		
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	90 – 264 VAC	AA disposable batteries and A/C wall plug adaptor, or AA rechargeable batteries	Same

Note 1:

Mode1's wavelength is the same as the predicate device 3 (K242151), Mode 2's wavelength is in the range of predicate device 1 (K101716). Therefore, the subject device and predicate device provide the same treatment benefit.

Note 2:

The intensity of mode 1(high brightness mode) is similar to that of predicate device 3 (K101716), which has an intensity of 50-80mW/cm^2. Furthermore, the red light's intensity is the same as K162763 (50mW/cm^2), and the NIR light's intensity is lower than that of K090008 (60mW/cm^2). Therefore, the Mode 1 of subject device will not raise any safety or effectiveness issues.

The intensity of mode 2(high brightness mode) is the same as that of predicate device 1 (K242151)'s model HD-44. The intensity of bedtime mode of Mode 1 and Mode 2 is similar to that of the predicate device 2(K232977), with a small difference of 3mW/cm^2.

Additionally, the subject device has already passed the testing regarding to standard IEC 60601-1 and IEC 60601-2-57. In conclusion, the device is safe and effective. The slight differences between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Final Conclusion:

The subject device is the same or similar to the legally marketed predicate device K242151, K232977 and K101716.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

KALA MINI 2.0 (Model: KALA-04) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/Significant Deviations	Test results
General requirements for basic safety and essential performance	IEC 60601-1:2005/AMD1:2012/AMD2:2020	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	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.	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 Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use	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.	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
Performance Test	The Performance Test Report performs the following tests on the finished product: 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 applied part of subject device will not have direct contact with the human body, but the back enclosure of device can contact to patient during normal use. And 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 10993-23 (Irritation).

3) Usability Testing

Usability testing was conducted on KALA MINI 2.0, 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, "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff"

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 K242151, K232977 and K101716.