May 30, 2025

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

Re: K250581
Trade/Device Name: KALA Red Light Face Mask (KALA-01)
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: April 29, 2025
Received: April 29, 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: 2025.05.30 15:14:04 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250581

Please provide the device trade name(s).

KALA Red Light Face Mask (Model: KALA-01)

Please provide your Indications for Use below.

The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the red and near-infrared spectrum and is intended for the use in the treatment of full-face wrinkles.

The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the blue region of the light spectrum and is intended for the use in the treatment of mild to moderate acne vulgaris of the face.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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.

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

Email: registrar@kaiyanmedical.com

2. Date of the summary prepared: May 30, 2025

3.Subject Device Information

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

Trade Name: KALA Red Light Face Mask

Model Name: KALA-01

Review Panel: General & Plastic Surgery

Product Code: OHS

Subsequent Product Codes: OLP

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: Dongguan Boyuan Intelligent Technology Co., Ltd.

Trade Name: LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)

Classification Name: Light Based Over the Counter Wrinkle Reduction

510(K) Number: K241857

Review Panel: General & Plastic Surgery

Product Code: OHS

Regulation Number: 878.4810

Regulation Class: II

5. Device Description

KALA Red Light Face Mask is a home wearable light-emitting diode phototherapy device with three proven wavelengths of light 630nm Red light, 830nm Near infrared red light and 465nm blue light, all of these lights are known to treat wrinkles and mild to moderate acne vulgaris of the face. Among them, the device emits energy in red and near-infrared spectrum to treat full-face wrinkles, emits energy in the blue region of the light spectrum to treat 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 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 be connected to a suitable mains outlet via a 2 or 3 pin input socket and wall plug. The KALA Red Light Face Mask cannot be operated while charging. The controller switches the LEDs ON/OFF and controls power to the mask. Switch the controller ON and allow the mask to run for Red + NIR or Blue modes and 10- or 20-minutes treatment time program. 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

The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the red and near-infrared spectrum and is intended for the use in the treatment of full-face wrinkles.

The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the blue region of the light spectrum and is intended for the use in the treatment of mild to moderate acne vulgaris of the face.

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 K221775**	**Predicate Device 2 K241857**	**Remark**
Company	Shenzhen Kaiyan Medical Equipment Co.,Ltd	Light Tree Ventures Europe B.V.	Dongguan Boyuan Intelligent Technology Co., Ltd.	--
Trade Name	KALA Red Light Face Mask	LED Light Therapy Mask	LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)	--
Classification Name	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	--
510(k) Number	TBD	K221775	K241857	--
Product Code	OHS, OLP	OHS, OLP	OHS, OLP, ILY	Same
FDA Device Classification	Class II	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Over the counter	Same
Intended Use / Indications for Use	The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the red and near-infrared spectrum and is intended for the use in the treatment of full-face wrinkles. The KALA Red Light Face Mask (Model: KALA-01) is an over-the-counter device that is intended to emit energy in the blue region of the light spectrum and is intended for the use in the	The LED Light Therapy Mask (Models: MK-78, MK-04) is an over-the-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, EL00003) is an over-the-counter device	KFB290, KFB291: Red light: Treatment of full-face wrinkles. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne.	Same

Elements of Comparison	Subject Device	Predicate Device 1 K221775	Predicate Device 2 K241857	Remark
	treatment of mild to moderate acne vulgaris of the face.	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.	Mixed light (Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne. KFB265, KFB293: Red+Infrared Light: Treatment of wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Amber light: Treatment of wrinkles.	
Intended location of use	Face	Face	Face	same
Energy Type	Light emitting diodes	Light emitting diodes	Light Emitting Diodes	Same
Wavelengths	Red: 630nm±10nm NIR: 830nm±10nm Blue: 465nm±10nm	1.MK-78, MK-04: Red: 630±5 nm NIR: 830nm 2.MK66-H, EL00003: Blue: 415nm, Red: 630nm +/- 5nm, NIR: 830nm	635nm ± 5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	Same
Total Intensity (mW/cm^2)	Mode1： Red: 20mw/cm^2 Infrared Red: 10mw/cm^2, Total: 30mw/cm^2 Mode2: Blue: 10mw/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	**KFB290, KFB291** Red: 25mW/cm^2; IR: 3mW/cm^2; Red+IR: 30mW/cm^2; Blue: 18mW/cm^2; Amber: 20mW/cm^2; Mixed light: 9mW/cm^2 **KFB265, KFB293** Red+IR: 25.5mW/cm2 Blue: 1.36mW/cm^2 Amber: 20mW/cm2	Similar Note 1
Treatment Time	10, 20 minutes treatment time program	10 minutes	For red, blue and red+infrared: 10, 20, 30 minutes for infrared, amber light and mixed light: 10, 20 minutes.	Same
Treatment protocol	3-5 times /week	Acne: 4 x weekly, 6 weeks; Wrinkles: 5 x weekly, 6 weeks	As above	Same

Elements of Comparison	Subject Device	Predicate Device 1 K221775	Predicate Device 2 K241857	Remark
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	-	Same
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Rechargeable Lithium-ion battery	Same

Note 1:

The intensity of mode 1 in the subject device is the same as predicate device 1 (K221775), which only emits two kinds of light: red light and infrared light. The intensity of mode 2 is similar to predicate device 2 (K241857). Additionally, the subject device is the same as predicate device 2 (K241857), both have single blue light mode to treat acne. The intensity of the subject device is similar to that of the predicate device 2 (18mW/cm2, K241857), with a small difference 8mW/cm2. In addition to this, model KFB265, KFB293 has an intensity 1.36mW/cm2, the intensity is much lower than that of the subject device. This indicate that the subject device is as safe and effective as products already on the market.

Furthermore, the subject device has already passed the testing regarding 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 K221775 and K241857.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

KALA Red Light Face Mask (Model: KALA-01) 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 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 Red Light Face 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, "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 K221775 and K241857.