July 30, 2025

Shenzhen Lifotronic Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401
China

Re: K251076
Trade/Device Name: Diode Laser Hair Removal Machine (models: T60A, T60B, T60C, T60D, T60E)
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: GEX
Dated: April 7, 2025
Received: April 8, 2025

Dear Ray Wang:

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: 2025.07.30 18:15:46 -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)*
K250761

Device Name
KALA Therapy Wand (Model: KALA-03)

Indications for Use *(Describe)*
The KALA Therapy Wand (Model: KALA-03) is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne. The red light is intended for the treatment of wrinkles, and the blue light is intended for the treatment of mild to moderate inflammatory acne.

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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510(k) Summary: K250761

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 (CEO)
Tel: +86-0755-82129361
Fax: +86-755-25024651
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

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: +86-0755-82129361
Fax: +86 755 25024651
Email:alaindijkstra@kaiyanmedical.com

2. Subject Device Information:

Trade Name: KALA Therapy Wand (Model: KALA-03)
Classification Name: Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP); Therapeutic massager (ISA)
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP, ISA
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K241718)

Sponsor: Shenzhen Aozemei Technology Co., LTD
Trade Name: Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)
Classification Name: Light Based Over the Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne (OLP)
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP

Regulation Number: 21 CFR 878.4810
Regulation Class: II
Predicate Device 2 (K161434**)**
Sponsor: Li-Tek Electronics Technologies
Trade Name: Photon Vibrating Massage Facial Aesthetic Device (Model: UI-200)
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Therapeutic massager (ISA)
Review Panel: General & Plastic Surgery
Product Code: OLP, ISA
Regulation Number: 21 CFR 878.4810
Regulation Class: II
Predicate Device 3 (K242700**)**
Sponsor: Shenzhen Nuon Medical Equipment Co., Ltd
Trade Name: Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B)
Classification Name: Light Based Over The Counter Wrinkle Reduction (OHS)
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

The KALA Therapy Wand (Model: KALA-03) is indicated for over-the-counter aesthetic use. The red light is intended for the treatment of wrinkles, and the blue light is intended for the treatment of mild to moderate inflammatory acne. The device is vibrating in red light model. The device is powered by a Lithium-Ion rechargeable battery, and it has a charging cable, USB charging stand, protective goggles, storage case and instruction manual.
The wand can be rotated 135 degrees in either direction.
There are two switches of the device: one function is red light to wrinkle removal and vibration for relax, the other function is blue light to treat mild to inflammatory acne.
The device will automatically shut down after 12 minutes of operation. The recommended treatment time is 3 minutes per area. After every three minutes of treatment, the device will vibrate to indicate the time. If you need to continue treatment, simply turn on the device again.

5. Intended Use / Indications for Use

The KALA Therapy Wand (Model: KALA-03) is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne. The red light is intended for the treatment of wrinkles, and the blue light is intended for the treatment of mild to moderate inflammatory acne.

6. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject device (K250761)	Predicate device (K241718)	Predicate device (K161434)	Predicate device (K242700)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Aozemei Technology Co., LTD	Li-Tek Electronics Technologies	Shenzhen Nuon Medical Equipment Co., Ltd	--
510 (K) Number	K250761	K241718	K161434	K242700	--
Device Name	KALA Therapy Wand (Model: KALA-03)	Micro-current Facial Beauty Device (AM-810B, AM-810W, AM-812B, AM-812W)	Photon Vibrating Massage Facial Aesthetic Device (Model: UI-200)	Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-59D, HD-70, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B)	--
OTC/Rx	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Same
Product Code	OHS, OLP, ISA	OHS, OLP	OLP, ISA	OHS, OLP	Same
Anatomical Sites	Entire Face	Face	Entire Face	Entire Face	Same
Environment of Use	Home	-	Home	Home	Similar
Regulation Number	21 CFR 878.4810 21CFR 890.5660	21 CFR 878.4810	21 CFR878.4810, 21CFR 890.5660	21 CFR 878.4810	Same
Indications for Use / Intended use	The KALA Therapy Wand (Model: KALA-03) is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne. The red light is intended for the treatment of wrinkles, and the blue light is intended for the treatment of mild to moderate inflammatory acne.	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	The Photon Vibrating massage Facial Aesthetic Device (Model: UI-200) is intended for over-the-counter use. LED functional mode - To emit energy in the blue and red region of the spectrum, specifically to treat mild to moderate acne on the face. - To emit energy in the blue region of the spectrum to treat mild to moderate	The Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A) is intended for the treatment of wrinkles for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-70) is intended for the treatment of	Same

Elements of Comparison	Subject device (K250761)	Predicate device (K241718)	Predicate device (K161434)	Predicate device (K242700)	Remark
			inflammatory acne. Vibrating massage functional mode As an electrically powered device intended for medical purposes to relieve minor aches and pains.	wrinkles and the mild to moderate inflammatory acne for over-the-counter cosmetic use. The Radiant Renewal Skincare Lid (Model: HD-59D, HD-72A, HD-73B, HD-116A, HD-53B) is intended for the treatment of the mild to moderate inflammatory acne for over-the-counter cosmetic use.	
Housing Materials of main unit	Aluminum	ABS, PC	ABS plastic+ stainless steel.	PC & PP & Stainless Steel & ABS & Silicon& Aluminum & Silicone	Different, note1
Power Source	Lithium-ion Battery: DC3.7V, 500mAh,1.85Wh	3.7V/600mAh Lithium battery	3.7V 1000mAh Li battery	Lithium battery: For models HD-59A, HD-59B, HD-59D, HD-72, HD-72A, HD-73A, HD-73B, HD-116, HD-116A, HD-53A, HD-53B: 3.7V, 55mAh, 0.204Wh For model HD-70: 3.7V, 95mAh, 0.3515Wh	Different, note 2
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Not applicable – this device is not sold sterile	Same

Elements of Comparison	Subject device (K250761)	Predicate device (K241718)	Predicate device (K161434)	Predicate device (K242700)	Remark
Type of Energy	LED	LED	LED	LED	Same
Treatment time	3 minutes per area,12 minutes per treatment, once a day.	-	1-20 mins	2 minutes per treatment	Different, note 3
Software/ Firmware /Microprocessor Control?	Yes	Yes	Yes	Yes	Same
LED wavelength	Red: 630nm Blue: 415nm	Red: 630±10nm Blue: 415±10nm Amber: 605±10nm	Red: 630±10nm, Blue: 415±10nm	HD-72: Red light mode: 630±10nm Yellow light mode: 590±10nm	Same
Irradiance	Red light:20mw/cm^2 blue light:15mw/cm^2	Red light: 2.5mW/cm^2 Amber light: 15mW/cm^2 Blue light: 1.4mW/cm^2	Red: 7.5 mW/cm^2 Blue: 22 mW/cm^2	HD-72 Red light mode: 630±10nm: 15~40mw/cm^2 Yellow light mode: 590±10nm: 8~30mw/cm^2	Different, note 4
Visible light LEDs	Yes	Yes	Yes	YES	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC60601-1-2	IEC60601-1-2	Same
Safety	Compliant with IEC 60601-1, IEC 60601-1-11, IEC 62471, IEC 60601-2-57	Compliant with IEC 60601-1:2005, IEC 60601-1-11, IEC60601-2-83 IEC 62133-2, IEC 62471	Compliant with IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57,	Compliant with IEC 60601- 1, IEC 60601-1-11, IEC 62471, IEC 0601-2-57	Same

Comparison of Key Technical Specifications

Characteristic – Red Light	Subject device (K250761)	Predicate device (K241718)	Predicate device (K161434)	Predicate device (K242700)
Wavelength	Red: 630nm	Red: 630±10nm Amber: 605±10nm	/	HD-72: Red light mode:

				630±10nm
Output intensity/Irradiance	Red light:20mw/cm^2	Red light: 2.5mW/cm^2 Amber light: 15mW/cm^2	/	HD-72 Red light mode: 630±10nm: 15~40mw/cm^2

Characteristic – Blue Light	Subject device (K250761)	Predicate device (K241718)	Predicate device (K161434)	Predicate device (K242700)
Wavelength	415nm	Blue: 415±10nm	Blue: 415±10nm	/
Output intensity/Irradiance	15mw/cm^2	1.4mW/cm^2	Blue: 22 mW/cm^2	/

Note1: Although the housing materials of main unit is different from the predicate devices, it complies with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-10 (Irritation). So the difference will not raise any safety or effectiveness issue.

Note2: Power source specifications are similar to the predicate devices. The subject device is in compliance with IEC 60601-1, IEC 60601-1-11, IEC 62133-2 and IEC 60601-1-2 requirement for the product.

Note 3: Treatment time of subject device is within the range of the treatment time of the predicate devices. The subject device is in compliance with IEC 60601-1, IEC 60601-1-11, IEC 62133-2 and IEC 60601-1-2 requirement for the product. So the difference will not raise any safety or effectiveness issue.

Note4: Although the irradiance is a little different from the predicate devices, they are within the range of previous cleared devices, so the differences will not raise any safety or effectiveness issue. The irradiance of the red light is in between the irradiance of K241718 and the irradiance of K242700; the irradiance of the blue light is in between the irradiance of K241718 and the irradiance of K161434.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical tests were performed on the subject device for validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- 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 1.0 2011-01 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2 Edition 1.0 2017-02 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 of the subject device are identical to the corresponding component materials of the previously cleared devices (K232863) 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) Software verification and validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff”. The software for this device was considered as a Basic Documentation Level, 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.

4) Usability validation

Usability testing was conducted on the KALA Therapy Wand (Models: KALA-03).

7.2 Summary of 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.

8. Date of the summary prepared: July 9, 2025

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K241718, K161434, and K242700.