October 30, 2025

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

Re: K252414
Trade/Device Name: Q-Renew LLLT Hair Growth Helmet (Q-HLMT-V1)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 30, 2025
Received: August 1, 2025

Dear Dijkstra Alain:

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: 2025.10.30 15:51:50 -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)*
K252414

Device Name
Q-Renew LLLT Hair Growth Helmet (Q-HLMT-V1)

Indications for Use *(Describe)*
The Q-Renew LLLT Hair Growth Helmet is indicated for the promotion of hair growth in males who have Norwood-Hamilton classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-ll, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.

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."

510(k) Summary
K252414

This summary of 510(k) 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.
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)
Establishment Registration Number:3011644607
Tel: +86 755 82129361
E-mail: alaindijkstra@kaiyanmedical.com

Distributor:
Company: Qure Skincare Pty Ltd
Address: Level 1,56 Clarence street NSW2000 Sydney Australia

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: registrar01@kaiyanmedical.com

2. Subject Device Information:

Device/Trade Name: Q-Renew LLLT Hair Growth Helmet (Q-HLMT-V1)
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number:21 CFR 890.5500
Regulation Class: II

3. Predicate Device Information

Predicate Device (K222081)
Sponsor: Remax Medi Tech(Shenzhen) Corporation
Device/Trade Name: ID-510 iRestore Elite
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Reference Device 1 (K200464)
Sponsor: LG Electronics Inc.

Trade Name: LG Pra.L Derma LD Scalp Care
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Reference Device 2 (K231321)
Sponsor: Shenzhen Kaiyan Medical Equipment Co.,Ltd.
Trade Name: NOOANCE LED AND LASERHELMET M-120 and M-282 PRO
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Reference Device 3 (K242363)
Sponsor: Shenzhen Kaiyan Medical Equipment Co.,Ltd.
Trade Name: HIGHERDOSE RED LIGHT HAT (HG-120K)
Classification Name: Infrared Lamp
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

4. Device Description

The Q-Renew LLLT Hair Growth Helmet is a non-invasive, at-home low-level laser/light therapy (LLLT) device designed to promote hair growth in both men and women. It uses a dual light system that combines laser diodes (wavelength 655nm) with LEDs (wavelengths 630nm, 660nm, and 680nm) to deliver optimal light absorption by the scalp.

The device consists of a Q-Renew LLLT helmet, a charging base and a USB-C charging cable.
The helmet features an adjustable fit, controlled by a rear adjustment wheel, and an intuitive LCD screen for operation. Users can:

- Start or pause treatments
- Select treatment zones
- Check battery status
- View remaining session time

The helmet has a power button for turning the device on/off. The device also includes smart sensors—removing the helmet automatically pauses the session, while repositioning it resumes treatment. Each session lasts 12 minutes, after which the device stop the treatment automatically.

5. Intended Use / Indications for Use

The Q-Renew LLLT Hair Growth Helmet is indicated for the promotion of hair growth in males who have Norwood-Hamilton classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.

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 and the applicable standards.

Elements of Comparison	Subject device	Predicate device (K222081)	Reference device 1 (K200464)	Reference device 2 (K231321)	Reference device 3 （K242363）	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Freedom Laser Therapy, Inc.	LG Electronics, Inc.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	--
510 (K) Number	**K252414**	**K222081**	**K200464**	**K231321**	**K242363**	--
Device Name	Q-Renew LLLT Hair Growth Helmet	ID-510 iRestore Elite	LG Pra.L Derma LD Scalp Care	NOOANCE LED AND LASER HELMET (Model: M-120, M-282 PRO)	HIGHERDOSE RED LIGHT HAT (HG-120K)	--
OTC/Rx	OTC	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OAP	OAP	OAP	OAP	OAP	Same
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Indications for Use /Intended use	The Q-Renew LLLT Hair Growth Helmet is indicated for the promotion of hair growth in males who have Norwood-Hamilton classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.	The ID-510 iRestore Elite is indicated to promote hair growth in males who have Norwood Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.	The LG Pra.L Derma LD Scalp Care is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes	The NOOĀNCE LED AND LASER HELMET is indicated to promote hair growth in males with androgenetic alopecia who have HamiltonNorwood Classifications of IIa-V and Fitzpatrick Classification of Skin Phototypes I to IV, and females with androgenetic alopecia who	The HIGHERDOSE Red Light Hat is a home wearable light-emitting diode phototherapy device with proven wavelengths of light 650nm±10nm Red light, which are used to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of	Same

Elements of Comparison	Subject device	Predicate device (K222081)	Reference device 1 (K200464)	Reference device 2 (K231321)	Reference device 3 （K242363）	Remark
			I to IV.	have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	
Irradiance source	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Light emitting diodes	Same
Number of diodes	LED:220 Laser:150	Laser:300 LED: 200	250	M-120: LDs: 51 LEDs: 69 M-282 PRO: LDs: 82 LEDs: 200	120 Red LEDs	Similar (Note 1)
Wavelength	LED: 630nm, 660nm, 680nm Laser:655nm	LED: 625 ± 10nm and 655 ± 10nm Laser: 680 ± 10nm	LED: 645-665nm Laser: 650nm-667nm	Laser: 650±5 nm Red light LED: 650±5nm	650±10nm	Similar (Note 1)
Power density (mw/cm^2)	3-5 mW/cm^2	Not publicly available	Not publicly available	M-120: approximately 1.3 mW/cm^2 M-282 PRO: approximately 2.8mW/cm^2	5 mW/cm^2	Similar (Note 3)
Treatment Time	12 minutes, Once per day, 3-7 times per week	12 minutes per treatment, to be used daily.	18 minutes or 27 minutes	25 minutes every other day for 16 weeks	10 minutes every other day for 16 weeks	Similar (Note 1)
Laser classification according to IEC 60825-1	Class 2	Laser Class 3R	Class 3R	Class 1C	/	Different (Note 2)

Elements of Comparison	Subject device	Predicate device (K222081)	Reference device 1 (K200464)	Reference device 2 (K231321)	Reference device 3 （K242363）	Remark
Power Supply	Lithium-ion battery	Lithium-ion battery	Lithium-ion battery	Lithium-ion battery	Rechargeable Lithium battery	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-2 IEC TS 60601-4-2 IEC 62471 IEC60825-1 IEC 62133-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC60825-1	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-1-2 IEC TR 60601-4-2 IEC60825-1	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 60601-1-2 IEC 62133-2	Same
Biocompatibility	All patient contacting materials comply with ISO 10993-5, ISO 10993-10, ISO10993-23	ISO 10993-5 ISO 10993-10	Unknown	ISO 10993-5, ISO 10993-10, ISO10993-23	ISO 10993-5, ISO 10993-10, ISO10993-23	Same

Comparison in Detail(s):

Note 1:
The subject device is slightly different from the predicate device in terms of wavelength and number of diodes, but these parameters remain very close to those of the predicate device and reference devices. These minor differences do not raise any issues of safety and effectiveness.

Note 2：
Although the subject device's laser classification (per IEC 60825-1) differs from that of the predicate device, it has undergone safety testing in accordance with IEC 60825-1 standards, and all test results comply with safety requirements. Therefore, this difference does not raise any safety or effectiveness concerns.

Note 3:
The subject device is slightly different from the predicate device in terms of power density, but it is within range of the power density reference device 2 and reference device 3. This minor difference does not raise any issues of safety and effectiveness.

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 to 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.
- IEC60601-2- 83: 2019 + AMD1: 2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- 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 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- IEC 62133-2:2017+AMD1:2021 Edition1.1 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 of Q-Renew LLLT Hair Growth Helmet (Model: Q-HLMT-V1) has been conformed to ISO 10993-5, ISO 10993-10 and ISO 10993-23.

3) Software verification and validation

Software verification and validation testing was conducted and documentation 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."

4) Usability Testing

Usability testing was conducted on the Q-Renew LLLT Hair Growth Helmet (Model: Q-HLMT-V1), the device complies with IEC 62366-1 and IEC 60601-1-6.

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 prepared: October 30, 2025

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as the legally marketed predicate device K222081.