October 9, 2025

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

Re: K252272
Trade/Device Name: ORA Method LED Gua Sha (GS-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, ISA
Dated: July 18, 2025
Received: July 22, 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: 2025.10.09 14:53:07 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252272

Device Name
ORA Method LED Gua Sha (GS-04)

Indications for Use *(Describe)*
The ORA Method LED Gua Sha (Model: GS-04) is an Over-the-Counter (OTC) device indicated to emit energy in red and infrared region of the spectrum for treatment of full-face and decolletage 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.

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510(k) Summary
K252272

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: +86-135-10378748
Fax: +86-755-25024651
E-mail: registrar01@kaiyanmedical.com

Distributor:

Company:KSR Venture, LLC(d.b.a ORA).
Address: 9 E 4th Street, New York, NY,10003,USA

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:

Trade Name: ORA Method LED Gua Sha, Model: GS-04
Classification Name: Light Based Over The Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS, ISA
Regulation Number:21 CFR 878.4810
Regulation Class: II

3.Predicate Device Information

Predicate Device 1 (K250761)

Sponsor: Shenzhen Kaiyan Medical Equipment Co.,Ltd
Trade Name: KALA Therapy Wand (Model: KALA-03)
Classification Name: Therapeutic massager ;Light Based Over The Counter Wrinkle Reduction;Over-The-Counter Powered Light Based Laser For Acne；
Review Panel: Physical Medicine Devices.General & Plastic Surgery
Product Code: OHS,OLP,ISA
Regulation Number: 21 CFR 890.5660,21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K242382)
Sponsor: ISMART DEVELOPMENTS LTD
Trade Name: décoLITE
Classification Name: Light Based Over The Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 3 (K242700)
Sponsor: Shenzhen Nuon Medical Equipment Co., Ltd
Radiant Renewal Skincare Lid (Model: HD-59A, HD-59B, HD-72, HD-73A, HD-116, HD-53A, HD-70, HD-59D, HD-72A, HD-73B,HD-116A,HD-53B)
Classification Name: Light Based Over The Counter Wrinkle Reduction;Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OHS,OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4.Device Description
The ORA Method LED Gua Sha (Model: GS-04) is a hand-held, battery-powered device used for the treatment of full-face and decolletage wrinkles by emitting LED red(630nm) and infrared(830nm) light. The device is powered by a Lithium-Ion rechargeable battery, and it has a charging cable,charging base, Goggles,storage bag and instruction manual.

The device have two functions:

A)Red and infrared irradiation function:The device emits energy in red and infrared region of the spectrum to reduce wrinkles on the face and decolletage;
B)Vibration and Gua Sha function. The device generates micro-vibration at a frequency of 200 Hz via its built-in micro motor. When used in conjunction with Gua Sha operation, it provides a soothing massage to the skin intended for relaxing the skin.
The recommended treatment time is 10 minutes per area. If you need to continue treatment, simply turn on the device again.

5.Intended Use / Indications for Use
The ORA Method LED Gua Sha (Model: GS-04) is an Over-the-Counter (OTC) device indicated to emit energy in red and infrared region of the spectrum for treatment of full-face and decolletage wrinkles.

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. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Comparison in Detail(s):

Item	Subject device	Predicate device 1	Predicate device 2	Predicate device 3	Remark
Trade name	ORA Method LED Gua Sha Model:GS-04	KALA Therapy Wand Model: KALA-03	DécoLITE	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	/
510 (k) number	K252272	K250761	K242382	K242700	/
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Kaiyan Medical Equipment Co.,Ltd	ISMART Developments Ltd	Shenzhen Nuon Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810, 21 CFR 890.5660	21 CFR 878.4810	21 CFR 878.4810	SE
Classification name	Light Based Over The Counter Wrinkle Reduction	Therapeutic massager ; 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;Over-The-Counter Powered Light Based Laser For Acne	SE
Product code	OHS, ISA	OHS,OLP,ISA	OHS	OHS,OLP	SE
Class	II	II	II	II	SE
Indications for use/ Intended use	The ORA Method LED Gua Sha (Model: GS-04) is an Over-the-Counter (OTC) device indicated to emit energy in red and infrared region of the spectrum for treatment of full-face and decolletage wrinkles.	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.	The décoLITE LED device is an over-the-counter device that is intended for the use in the treatment of wrinkles in the decolletage area.	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 wrinkles and the mild to moderate inflammatory acne for	SE,Note1

				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.	
OTC or prescription	OTC	OTC	OTC	OTC	SE
Basic unit characteristics					
Power supply	Main unit: 3.7V, 450mAh lithium battery Input: 100-240Va.c., 50/60Hz Output: 5Vd.c, 1A	Main unit: 3.7V,500mAh lithium battery,1.85Wh Adapter Input:100-240Va.c., 50/60Hz	Not available	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	SE,Note2
Output specifications					
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)	SE
Wavelength	Red: 630nm NIR:830nm	Red: 630nm Blue: 415nm	Red:630nm±10nm NIR: 830nm±10nm	HD-72: Red light mode: 630±10nm Yellow light mode: 590±10nm	SE,Note 3
Irradiance	20-35 mW/cm^2 total	Red light:20mw/cm2 Blue light:15mw/cm2	30 mW/cm^2 total	HD-72 Red light mode: 630±10nm:15~40mw/cm2	SE

				Yellow light mode: 590±10nm:8~30mw/cm2	
Additional features					
Treatment duration	10 minutes for each part	3 minutes per area,12 minutes per treatment, once a day	10 minutes per area	2 minutes per treatment	SE
Materials of skin-contacting components	PC,ABS,TPU	Aluminum	Not knowable	PC& PP &Stainless Steel &ABS &Silicon&Aluminum & Silicone	SE,Note 4
Biocompatibility feature	ISO10993-5, ISO 10993-10, ISO 10993-23	ISO10993-5, ISO 10993-10,	Not public	ISO10993-5, ISO 10993-10,	SE
Electrical safety	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 60601-2-83;	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	SE

Comparison in Detail(s):

Note 1:

The indications for use of the subject device is similar with predicate device 1,2 and 3 .So, these slight differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Power Supply" is different from the predicate devices, but they all complied with the IEC60601-1,IEC 60601-1-11 and IEC 60601-1-2 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issue.

Note 3:

Although the"Irradiances" and the treatment duration are little different from the predicate devices, But the Wavelength are similar.And they all complied with the IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-83 safety standards’ requirements.So, these differences will not raise any safety or effectiveness issue.

Note 4:

Although the ‘‘Materials of skin-contacting components’’ are different from the predicate devices, But they all complied with the ISO 10993-5,ISO 10993-10, ISO 10993-23 bio-commformity standard’ requirements.So, these differences will not raise any safety or effectiveness issue.

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.
- IEC 60601-2-83:2019+AMD1:2022 Edition 1.1 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 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)Biological Compatibility Statement

The component of the ORA Method LED Gua Sha (Model: GS-04) has been conformed to ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

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." The software for this device is 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 the delivery of appropriate medical care that would likely lead to Minor Injury.

4)Usability validation

Usability testing was conducted on the ORA Method LED Gua Sha (Model: GS-04), which 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 of the summary prepared: September 12, 2025

9. <u>Final Conclusion</u>

The subject device is equally safe, effective, and performs as well or better than the legally marketed predicated devices K250761,K242382 and K242700.