May 22, 2025

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

Re: K250532
Trade/Device Name: Solawave 2-in-1 Skincare Mini (61043)
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
Dated: February 22, 2025
Received: February 24, 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: 2025.05.22 15:29:33 -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)*
K250532

Device Name
Solawave 2-in-1 Skincare Mini (Model: 61043)

Indications for Use *(Describe)*
The Solawave 2-in-1 Skincare Mini (Model: 61043) is an over-the-counter device that emits energy in the red and infrared spectrum for treating wrinkles on the face and decolletage.

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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K250532
510(k) Summary

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
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
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Tel: +86-135-10378748
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E-mail: registrar01@kaiyanmedical.com

Distributor:

Company: Solawave Inc.
Address: 3633 Lenawee Avenue Suite 100 Los Angeles, CA 90016 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:

Common/Trade Name: Solawave 2-in-1 Skincare Mini (Model: 61043)
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

3. Predicate and Reference Device Information

Predicate Device (K213841)

Sponsor: Premier North America Inc
Trade Name: ENEO TOTALE
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

Reference Device 1 (K241102)
Sponsor: FOREO, Inc.
Trade Name: Luna™ 4 plus
Classification Name: Light Based Over the Counter Wrinkle Reduction;Transcutaneous electrical nerve stimulator for pain relief.
Review Panel: General & Plastic Surgery
Product Code: OHS,NFO
Regulation Number: 21 CFR 878.4810, 21 CFR 882.5890
Regulation Class: II
Reference Device 2 (K202055)
Sponsor: Heat In A Click LLC
Trade Name: Looper
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
Reference Device 3 (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

4. Device Description

The Solawave 2-in-1 Skincare Mini (Model: 61043) is a hand-held, battery-powered device that reduce wrinkles by emitting LED red light (630nm) and infrared light (830nm). The device is powered by a Lithium-Ion rechargeable battery, and it comes with a charging cable, storage bag, and instruction manual.

The Solawave 2-in-1 Skincare Mini is a revolutionary device that offers two simultaneous approaches for your skin routine in one handheld device:
1. Red and Near-Infrared Light Therapy
2. Warming function (This function is not for medical purpose.)

5. Intended Use / Indications for Use

The Solawave 2-in-1 Skincare Mini (Model: 61043) is an over-the-counter device that emits energy in the red and infrared spectrum for treating wrinkles on the face and decolletage.

6. Comparison to predicate and reference 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 (K213841)	Reference device 1 (K241102)	Reference device 2 (K202055)	Reference device 3 (K242382)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Premier North America Inc	FOREO, Inc.	Heat In A Click LLC	ISMART Developments Ltd	--
510 (K) Number	**K250532**	**K213841**	**K241102**	**K202055**	**K242382**	--
Device Name	Solawave 2-in-1 Skincare Mini	ENEO TOTALE	Luna™ 4 plus	Looper	décoLITE	--
Model	61043	unknown	Unknown	ZX-579S	/	--
OTC/Rx	OTC	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OHS	OHS	OHS,NFO	OHS, OLP	OHS	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 882.5890	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use / Intended use	The Solawave 2-in-1 Skincare Mini (Model: 61043) is an over-the-counter device that emits energy in the red and infrared spectrum for treating wrinkles on the face and decolletage.	ENEO TOTALE is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	1. The Red + IR light is intended to treat periorbital wrinkles 2. The microcurrent is intended to treat facial stimulation	Looper (Model: ZX-579S) is a hand-held device for over-the Counter aesthetic purposes. The Photon mode red light is indicated for the use in Treating wrinkles on the face.	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.	Similar (Note 1)
Intended Location Use	Face, decolletage	Face	Face	Face	Decolletage (upper chest)	Similar (Note 2)

Elements of Comparison	Subject device	Predicate device (K213841)	Reference device 1 (K241102)	Reference device 2 (K202055)	Reference device 3 (K242382)	Remark
Power Source	Lithium battery: DC 3.7V, 450mAh, 1.665Wh	Adaptor:100~240V AC 50/60Hz 2.4A Lithium battery: 3.75Vdc, 3000 mAh	Internal rechargeable Lithium battery	DC 3.7V 1000mA Li battery	Li battery	Similar (Note 3)
Irradiance source	LED	LED	LED, micro current	LED	LED	Same
Handheld	Yes	Yes	Yes	Yes	No(Mask type)	Similar
Dose/per time(J/cm^2)	7.2~9.9	37.5~52.5	3.78~15.12	9.9	18	Similar (Note 4)
LED wavelength	Red: 630nm ± 10nm Infrared: 830nm ± 10nm	Red: 633nm± 5nm Infrared:830nm± 5nm	RED light:633nm± 10nm Red+IR: 633+10nm/850nm±10nm	Red: 630±00nm	Red: 630nm ± 10nm NIR: 830nm ± 10nm	Similar (Note 4)
Irradiances	RED+IR: 40-55 mW/cm²	69mW/cm^2 for 633nm 56mW/cm^2 for 830nm	RED+IR: 63 mW/cm²	Red light: 55mW/cm^2±10 %	30mW/cm2 total	Similar (Note 4)
Treatment Time	3 minutes per treatment area	5-7 minutes on each treatment zone For the first month (4 weeks)treatment should be performed 3 times a week for 15-20 minutes each time	1-4 min (adjustable) per treatment	3 minutes per target area	600 seconds (10 minutes) 5× weekly, 6 weeks	Similar (Note 4)

Elements of Comparison	Subject device	Predicate device (K213841)	Reference device 1 (K241102)	Reference device 2 (K202055)	Reference device 3 (K242382)	Remark
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 62471	Compliant with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC60601-2-10	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57 IEC 60601-2-83 IEC 62471	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10 ISO 10993-23	ISO10993-5 ISO10993-10	unknown	Same

Comparison in Detail(s):

Note 1:
The Intended use of subject device is to treat wrinkle on the face, which is slightly different from the predicate device and reference device 1 (which treat periorbital wrinkles); However, it is the same as reference device 2, which is indicated for the entire face wrinkle treatment and both of them are hand held LED device.

Note 2:
The intended location use of the subject device is for face and decolletage, which is same as the predicate device, reference device 1, reference device 2 (for face) and reference device 3 (for decolletage).

Note 3:
The power supply for the subject device is a little different from that of the predicate device, however the lithium battery of the subject device has been tested under standard IEC 62133-2, so this difference should not raise any safety/effectiveness issues.

Note 4:
The subject device is a little different from the predicate device in terms of “Treatment Time”,“Dose/per time” and “Irradiances”, however they have the same LED wavelengths; And the “Treatment time”, “Dose/per time” and “Irradiances” of the subject device are very close to those of reference devices 1 and 2; so it can be concluded that the subject device can achieve the same treatment effect (wrinkle treatment) as the predicate and reference devices. In addition, all of them have passed the tests of IEC 60601-1,IEC 60601-1-11 and IEC 60601-2-57, these differences will not raise any new safety or effectiveness issues.

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 60601-2-57 Edition 2.0 2023 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 62133-2:2017+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 the Solawave 2-in-1 Skincare Mini (Model: 61043) 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." 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.

7.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k).

8. Date Prepared: May 22, 2025

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as the legally marketed predicate device, cleared under K213841, Class II (21 CFR 878.4810), product code OHS.