June 16, 2026

Shenzhen Kaiyan Medical Equipment Co., Ltd.
Alain Dijkstra
Official Correspondent
Bldg.#3 And Bldg.#5, 40th Of Fuxin St.
Huaide Community Fuyong Town, Baoan District
Shenzhen, Guangdong 518103
China

Re: K254025
Trade/Device Name: LED Neck Beauty Mask (ZLD-66A,ZLD-90E,ZLD-130,ZLD-180H)
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: December 16, 2025
Received: December 16, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.16 19:32:49 -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)*
K254025

Device Name
LED Neck Beauty Mask (ZLD-66A,ZLD-90E,ZLD-130,ZLD-180H)

Indications for Use *(Describe)*
M1 is an over-the-counter device that is intended for emit energy in the red and infrared spectrum for use for the treatment of full face and decolletage wrinkles.
M2,M3,M5 is an over-the-counter device that is intended for emit energy in the red,infrared, yellow spectrum for use for the treatment of full face wrinkles.
M4 is intended for over-the-counter use to treat mild to moderate inflammatory acne on the face.

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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"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."

K254025 - 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 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

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: LED Neck Beauty Mask, Model: ZLD-180H;ZLD-130;ZLD-90E;ZLD-66A
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

3. Predicate Device Information

Predicate Device 1 (K240089)

Sponsor: Shenzhen Kaiyan Medical Equipment Co., Ltd
Trade Name: Face Patches
Classification Name: Light Based Over the Counter Wrinkle Reduction;Over-The-Counter Powered Light Based Laser For Acne;Laser surgical instrument for use in general and plastic surgery and in dermatology.
Review Panel: General & Plastic Surgery
Product Code: OHS,OLP,GEX
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2 (K243492)

Sponsor: Shenzhen Ulike Smart Electronics Co.,Ltd.
Trade Name: Ulike Reglow Light Therapy Device

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

Predicate 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 LED Neck Beauty Mask (Model: ZLD-66A/ZLD-90E/ZLD-130/ZLD-180H) is a wearable, battery-powered device used for treatment of mild to moderate acne on the face, and wrinkles around the face and decolletage by emitting LED red(630nm),infrared(830nm),blue(465nm) and yellow(590nm)light. The device is powered by a Lithium-Ion rechargeable battery, and it has charging cable,adjustable Velcro,goggles, storage bag and instruction manual.

The device has only one button to power on/off and switch the modes,press long to power on/off,press short to switch the treatment modes.

The recommend treatment time is 10min per area, when the user choose the mode and treatment automatically completed after 10minutes.If you need to continue treatment, simply turn on the device again.

5. Intended Use / Indications for Use

M1 is an over-the-counter device that is intended for emit energy in the red and infrared spectrum for use for the treatment of full face and decolletage wrinkles.
M2,M3,M5 is an over-the-counter device that is intended for emit energy in the red,infrared,yellow spectrum for use for the treatment of full face wrinkles.
M4 is intended for over-the-counter use to treat mild to moderate inflammatory acne on the face.

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.

Elements of Comparison	Subject device	Predicate device 1 (K240089)	Predicate device 2 (K243492)	Predicate device 3 (K242382)	Remark

Elements of Comparison	Subject device	Predicate device 1 (K240089)	Predicate device 2 (K243492)	Predicate device 3 (K242382)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Ulike Smart Electronics Co.,Ltd.	ISMART Developments Ltd	--
510 (K) Number	K254025	**K240089**	**K243492**	**K242382**	--
Device Name	LED Neck Beauty Mask	Face Patches	Ulike Reglow Light Therapy Device	décoLITE	--
Model	ZLD-180H; ZLD-130; ZLD-90E; ZLD-66A	MT-12MA, MT-12MC	UM10	/	--
OTC/Rx	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Same
Product Code	OHS+OLP	OHS,OLP,GEX	OHS+OLP	OHS	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use / Intended use	M1 is an over-the-counter device that is intended for emit energy in the red and infrared spectrum for use for the treatment of full face and decolletage wrinkles. M2,M3,M5 is an over-the-counter device that is intended for emit energy in the red,infrared,yellow spectrum for use for the treatment of full face wrinkles. M4 is intended for over-the-counter use to treat mild to moderate inflammatory acne on the face.	Face Patches (Model: MT-12MA) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne. Face Patches (Model: MT-12MC) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne and full-face wrinkles (including periorbital wrinkles).	Ulike Reglow Light Therapy Device is an over the counter device that is intended for use in the treatment of full face wrinkles and 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.	Similar (Note 1)

Elements of Comparison	Subject device	Predicate device 1 (K240089)	Predicate device 2 (K243492)	Predicate device 3 (K242382)	Remark
Intended Location Use	Face, decolletage	Face	Face	Decolletage (upper chest)	Similar (Note 2)
Power Source	Lithium battery: 7.4V, 2600mAh,19.24W	Controller: 3.6V, 65mAh lithium battery, 0.234Wh	Controller:3.7V,2600mAh lithium battery, 9.62Wh	Not available	Similar (Note 3)
Irradiance source	LED	LED	LED	LED	Same
LED wavelength	Winkle For face and decolletage: M1:630+830 For face: M2:830+590 M3:630+590 M5:630+830+590 Acne M4:630+465	MT-12MA: 630±10nm 415+10nm MT-12MC: 415nm±10nm, 630nm ±10nm, 830nm ±10nm, 590nm ±10nm	465nm, 590nm, 630nm,830nm	Red: 630nm ± 10nm NIR: 830nm ± 10nm	Similar (Note 4)
Irradiances(mw/cm^2)	465nm:8-12 mW/cm^2, 630nm:8-12 mW/cm^2, 830nm:10-14mW/cm^2, 590nm:6-10 mW/cm^2	For MT-12MA: 630nm:5 415nm:25 630+415nm:30 For MT-12MC 630nm(type 1):5 415nm: 25 Mode 1-total: 30 830nm:15 630nm(type 2):20 Mode 2-total: 35 Mode 3-590nm:35	1-40	30 total	Similar (Note 4)
Treatment Time	10mins per treatment	For MT-12MA (630+415nm):3 minutes per treatment For MT-12MC (mode 1 - 630+415nm):3minutes per treatment	Not available	600 seconds (10 minutes) 5× weekly, 6 weeks	Similar (Note 4)

Elements of Comparison	Subject device	Predicate device 1 (K240089)	Predicate device 2 (K243492)	Predicate device 3 (K242382)	Remark
		For MT-12MC (mode 2 - 630+830nm):9minutes per treatment For MT-12MC(mode 3 - 590nm):21 minutes per treatment			
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-83 IEC 62471	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 60601-2-57, IEC 60601-2-83 IEC 62471	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	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23	ISO10993-5 ISO10993-10 ISO 10993-23	unknown	Same

Comparison in Detail(s):

Note 1:
The Intended use of subject device is to treat mild to moderate acne on the face, and wrinkles around the face and decolletage, which is slightly different from predicate devices 1,2 and 3 .

Note 2:
The intended location use of the subject device is for face and decolletage, which is same as the predicate device 1,2(for face),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 2 in terms of “Treatment Time” and “Irradiances”, however they have the same LED wavelengths ; And the “Treatment time”, “wavelength” and “Irradiances” of the subject device are very close to those of predicate device 1, 3; so it can be

concluded that the subject device can achieve the same treatment effect (wrinkle treatment and mild to moderate acne)as the predicate devices. In addition, all of them have passed the tests of IEC 60601-1,IEC 60601-1-11 and IEC 60601-2-83, 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 60601-2-83:2019+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 LED Neck Beauty Mask (Model: ZLD-66A,ZLD-90E,ZLD-130,ZLD-180H) 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 basic 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 validation

Usability testing was conducted on the LED Neck Beauty Mask(Model: ZLD-180H;ZLD-130;ZLD-90E;ZLD-66A).

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: June 4, 2026

9. Final Conclusion

The subject device is equally safe, effective, and performs as well or better than the legally marketed predicated devices K240089,K243492,K242382.