August 14, 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: K251012
Trade/Device Name: TRUDERMAL Pro (ZLD-390)
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, ILY
Dated: August 14, 2025
Received: August 14, 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: 2025.08.14 17:45:25 -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)*
K251012

Device Name
TRUDERMAL Pro, Model: ZLD-390

Indications for Use *(Describe)*
TRUDERMAL Pro (Model: ZLD-390) is an over-the-counter(OTC) device that delivering targeted phototherapy using three wavelengths(blue:415nm, red:630nm, Infrared(IR):850nm):

Red light: Reduces full-face wrinkles.
Blue light: Treats mild to moderate inflammatory acne.
IR light: Provides topical heating for the purpose of elevating tissue temperature, temporarily relieving minor muscle and joint pain, arthritis and muscle spasms; relieving stiffness; promoting relaxation of muscle tissues and temporarily increasing local blood circulation.

Mixed lights:
Red+IR light: Reduces full-face wrinkles.
Blue+Red light:Treats 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.

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: alaindijkstra@kaiyanmedical.com

Distributor:

Company: Trudermal Pty Ltd
Address: Level 20, 181 William Street Melbourne VIC 3000 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:

Trade Name: TRUDERMAL Pro, Model: ZLD-390
Classification Name: Over Based Over The Counter Powered Light Based Laser For Acne (OLP), Light The Counter Wrinkle Reduction (OHS) and Lamp Infrared, Therapeutic Heating (ILY)
Review Panel: General & Plastic Surgery
Product Code: OLP,OHS,ILY
Regulation Number:21 CFR 878.4810, 21 CFR 890.5500
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K212275)
Sponsor: Aesthetic Technology Ltd.
Trade Name: Dermalux Flex MD
Classification Name: Over Based Over The Counter Powered Light Based Laser For Acne (OLP), Light The Counter Wrinkle Reduction (OHS) and Lamp Infrared, Therapeutic Heating (ILY)
Review Panel: General & Plastic Surgery
Product Code: OLP,OHS,ILY
Regulation Number: 21 CFR 878.4810,21 CFR 890.5500
Regulation Class: II

Predicate Device 2 (K223544)
Sponsor: Guangdong Newdermo Biotech Co.,Ltd
Trade Name: LED light therapy mask (FM-01, FM-02, FM-03)
Classification Name: Over Based Over The Counter Powered Light Based Laser For Acne (OLP), Light The Counter Wrinkle Reduction (OHS) and Lamp Infrared, Therapeutic Heating (ILY)
Review Panel: General & Plastic Surgery
Product Code: OLP,OHS,ILY
Regulation Number: 21 CFR 878.4810,21 CFR 890.5500
Regulation Class: II

Predicate Device 3 (K242789)
Sponsor: Dongguan Laiguang Electronic Technology Co.,Ltd.
Trade Name: Bestqool LED therapy device Model: LMK-001LMK-004LMK-005LMK-006
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 4 (K221775)
Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LED Light Therapy Mask (Model: MK-78, MK-04, MK66-H, EL00003)
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 TRUDERMAL Pro is an over-the-counter LED light therapy medical device. The device emits specific wavelengths of low level, narrow band light for the treatment of certain dermatological and musculoskeletal indications. The wavelengths used in the TRUDERMAL Pro system are Blue 415nm, Red 630nm and Near Infrared 850nm.

The device consists of a TRUDERMAL Pro (with LED flexible silicone panel, Controller and AC/DC adapter), power cable, and 2 base seats, a pair of eye protectors.

The TRUDERMAL Pro enables treatment of the face and the body via a LED flexible silicone panel.The system is operated by a controller and treatments can be performed by selecting different wavelengths. The light is generated by Light Emitting Diodes(LED's) that are contained within the LED flexible silicone panel. The LED panel can be placed into the Base, holding in the appropriate position to administer a facial treatment. For use on the body,the LED panel is removed from the Base unit and placed over the appropriate body part.

The device is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The device does not require checks on the light output as the LEDs do not dim with age to any practical extent.

5. Intended Use / Indications for Use

TRUDERMAL Pro (Model: ZLD-390) is an over-the-counter(OTC) device that delivering targeted phototherapy using three wavelengths(blue:415nm, red:630nm, Infrared(IR):850nm):

Red light: Reduces full-face wrinkles.

Blue light: Treats mild to moderate inflammatory acne.

IR light: Provides topical heating for the purpose of elevating tissue temperature, temporarily relieving minor muscle and joint pain, arthritis and muscle spasms; relieving stiffness; promoting relaxation of muscle tissues and temporarily increasing local blood circulation.

Mixed lights:

Red+IR light: Reduces full-face wrinkles.

Blue+Red light:Treats 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 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 (K212275)	Predicate device 2 (K223544)	Predicate device 3 (K242789)	Predicate device 4 (K221775)	Remark
Manufacturer	Shenzhen Kaiyan Medical Equipment Co., Ltd	Aesthetic Technology Ltd.	Guangdong Newdermo Biotech Co.,Ltd	Dongguan Laiguang Electronic Technology Co.,Ltd.	Light Tree Ventures Europe B.V.	--
510 (K) Number	Applying	K212275	K223544	K242789	K221775	--
Device Name	TRUDERMAL Pro	Dermalux Flex MD	LED light therapy mask	Bestqool LED therapy device	LED Light Therapy Mask	--
Model	ZLD-390	/	/	LMK-001LMK-004LMK-005LMK-006	MK66-H	--
OTC/Rx	OTC	OTC	OTC	OTC	OTC	Same
Regulation Class	Class II	Class II	Class II	Class II	Class II	Same
Product Code	OHS, OLP, ILY	OLP, OHS, ILY	OHS, OLP,ILY	OHS,OLP	OHS, OLP	Same
Regulation Number	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	21CFR878.4810	21CFR878.4810	Same
Indications for Use / Intended use	TRUDERMAL Pro (Model: ZLD-390) is an over-the-counter(OTC) device that delivering targeted phototherapy using three wavelengths(blue:415nm, red:630nm, Infrared(IR):850nm): **Red light**: Reduces full-face wrinkles. **Blue light**: Treats mild to moderate	Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature, for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue, and to temporarily increase	Red light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Infrared light: Provide topical heating for the purpose of elevating tissue temperature; arthritis and muscle	This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.	The LED Light Therapy Mask (Models: MK-78, MK-04) is an over the counter device that is intended for the use in the treatment of full-face wrinkles. The LED Light Therapy Mask (Models: MK66-H, EL00003) is an over the counter device intended to	Same

	inflammatory acne. **IR light:** Provides topical heating for the purpose of elevating tissue temperature, temporarily relieving minor muscle and joint pain, arthritis and muscle spasms; relieving stiffness; promoting relaxation of muscle tissues and temporarily increasing local blood circulation. **Mixed lights**: Red+IR light: Reduces full-face wrinkles. Blue +Red light:Treats mild to moderate inflammatory acne.	local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. Intended to emit energy in the red and infrared spectrum for the use in dermatology for the treatment of periorbital and full face wrinkles.	spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. Mixed light: Treatment of mild to moderate inflammatory acne.		emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LED Light Therapy Mask (Models: MK66-H, EL00003) is an over the counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	
Intended Location Use	Face, body	Face, body	Face, body	Face	Face	same
Power Source	Adaptor Input: 100-240Vac, 50-60Hz,0.8~~A~~ Output: 12V 3A	100-240Vac, 50/60Hz, 4.6 - 1.85A, 460-430W	Input: 100-240 V~, 50/60 Hz, 0,25 A Output: DC 5 V, 500 mA	Input:100-240Vac, 0.6A, 50/60Hz	Rechargeable Lithium battery	Same
Irradiance source	LED	LED	LED	LED	LED	Same
Dose(J/cm^2)	Blue:7.2-12J/cm^2 Red:12-18J/cm^2 IR: 7.2-12J/cm^2 Mixed light: Blue+Red:19.2-24J/cm^2 Red+IR: 9.2-24J/cm^2	Red: 20J/cm^2 Blue: 10J/cm^2 NIR: 10J/cm^2	Red:1.8-2.7J/cm^2 Blue:1.8-3.6J/cm^2 Infrared light:1.8-3.6J/cm^2 Mixed light:8.1-10.8J/ cm^2	13.5 J/cm^2±25%	MK66-H,EL00003: Blue/Red: 26.4J/cm^2 Red/NIR: 18J/cm^2	Similar (Note 1)

LED wavelength	Blue: 415±10 nm Red: 630±10 nm IR: 850±10nm Mixed light: Blue+Red:415nm+630nm Red+IR:630nm+850nm	Blue light: 415nm±5nm Red light: 633nm±5nm NIR light: 830nm±5nm	Blue: 460nm Red: 620nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Blue :415nm±10nm Red :635nm±10nm+ NIR:850nm±10nm	MK66-H, EL00003: Blue: 415nm, Red: 630nm +/-5nm, NIR: 830nm	Similar (Note 1)
Irradiances	Blue:6-10 mW/cm² Red:10-15 mW/cm^2 IR:6-10 mW/cm² Mixed light: Blue+Red: 16-20 mW/ cm² Red+IR:16-20 mW/cm²	Blue - 415nm (5.52mW/cm^2) Red - 633nm (11.5mW/cm^2) NIR - 830nm (5.5mW/cm^2)	Red light: 2.0~3.0 mW/cm^2 Blue light:2.0~4.0 mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	7.5mw/cm^2±25%	1.MK-78: 20-30 mw/ cm2 2.MK-04: 30mw/cm2 3.MK66-H, EL00003: (1)Blue/Red 44 mw/ cm2 (2)Red/NIR 30 mw/ cm2	Different (Note 1)
Treatment Time	20 min per treatment Acne and Wrinkles: 3-4x weekly; 4 wks. Pain relief: 3x weekly	Up to 30 minutes Acne and Wrinkles: 3-4x weekly; 4 wks. Pain relief: 3x weekly	Manual Mode: 15minutes each time, Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2 treatment a week once the results shown.	30-60 minutes session 4 times a week 4 weeks	10 minutes per treatment Acne: 4 x weekly, 6 weeks; Wrinkles: 5 x weekly, 6 weeks	Similar (Note 1)
Electrical Safety	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 62471	IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, 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 62471	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	ISO10993-5 ISO10993-10	Not stated	ISO10993-5 ISO10993-10	Same

Comparison in Detail(s):

Note 1:

The subject device and predicate device have the same indications for use, working principle and conformance standards, etc. The subject device's wavelengths, treatment time, irradiance and radiation dose are similar and close to those of the predicate devices. For mixed light of subject device, the wavelength,irradiance and radiation dose are similar with the predicate device 1(K212275) and predicate device 4(K221775, model:MK66-H); Furthermore, performance data supports that the subject device is safe and as effective as the predicate devices for its intended use. Therefore, the minor differences do not raise new questions 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.
- 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 TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.

2) Biocompatibility test

The component materials of the TRUDERMAL Pro (Model: ZLD-390), including the inner surface of panel, controller enclosure, and eye protectors, are identical in formulation, processing, sterilization and geometry to the corresponding components in the following previously cleared devices:

- LED Light Therapy Mask (Models:MK-66H) for the inner surface of mask, clarified in K221775 on December 20, 2022.
- Aduro Light Therapy Handheld (Models: HD-03A, HD-25A, HD-07A) for the controller enclosure, clarified in K203271 on July 21, 2021.
- DemarkQ WOW (PB-B) for the eye protectors,clarified in K203214 on July 22, 2021

No additional chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, or mold release agents) have been added. Therefore, based on this information, the subject device can comply with the biocompatibility requirements of ISO10993-5(Cytotoxicity), ISO10993-10(Sensitization), and IS0 10993-23 (Irritation).

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.”

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: August 13, 2025

9. Final Conclusion

The subject device is as safe, as effective and performs as well as the legally marketed predicate devices K212275, K223544,K242789 and K221775.