March 4, 2026

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

Re: K253878
Trade/Device Name: LUSTRE GoGlow Advanced LED Patches (PR8001, PR9001)
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: OLP
Dated: November 21, 2025
Received: December 4, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.03.04 16:02:16 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253878

Please provide the device trade name(s).

LUSTRE GoGlow Advanced LED Patches (PR8001, PR9001)

Please provide your Indications for Use below.

LUSTRE GoGlow Advanced LED Patches (Model: PR8001, PR9001) is an Over-the-Counter (OTC) device that emits energy in the blue and red spectrum for the treatment of mild to moderate inflammatory acne.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary of K253878

This summary of 510(k) is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Company 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)
E-mail: registrar01@kaiyanmedical.com

Manufacturer:

Company Name: Lustre Skin Ltd
Establishment Registration Number: 3018188770
Address: Alba Innovation Centre, Alba Campus, Livingston Scotland, UK, EH547GA
Phone: +44 (0)1506 592239
Contact Person (including title): Blessing Nwabude, Head of Regulatory
Email: Blessing.Nwabude@Lustreskin.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:

Device/Trade Name: LUSTRE GoGlow Advanced LED Patches(Model: PR8001, PR9001)
Classification Name: Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OLP
Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device (K230720)

Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LUSTRE 3XPRESS Light Beauty Therapy patches, model: PR6001, PR5001
Classification Name: Over-The-Counter Powered Light Based Laser For Acne.
Review Panel: General & Plastic Surgery
Product Code: OLP
Regulation Number: 21 CFR 878.4810

Regulation Class: II

Reference Device(K160691)

Sponsor: Zuko, Inc.

Trade Name: Acne Light Therapy Wand

Classification Name: Over-The-Counter Powered Light Based Laser For Acne.

Review Panel: General & Plastic Surgery

Product Code: OLP

Regulation Number: 21 CFR 878.4810

Regulation Class: II

4. Device Description

The LUSTRE GoGlow Advanced LED Patches (Model: PR8001, PR9001) is an over-the-counter light emitting diode (LED) device indicated for the treatment of mild to moderate acne. It works by emitting energy in the blue (415nm) and red (630nm) spectrum. Each patch incorporates 24 LEDs with a power intensity of approximately 30 mW/cm^2.

The two models differ only in shape: the PR9001 is triangle, while the PR8001 is bean-shaped.

The device package includes two LED patches, two rechargeable controllers, a charging case, a USB cable, 56 Mini Dots(for holding the patch safely to the skin), a pair of goggles and a user manual. To use, simply connect a controller to each patch via the built-in magnets, apply the patches to the targeted skin area using the Mini Dots, then press and hold the power button on the controller to activate the device and start the treatment session. The patches will automatically shut off after the 3-minute session is complete.

5. Intended Use / Indications for Use

LUSTRE GoGlow Advanced LED Patches (Model: PR8001, PR9001) is an Over-the-Counter (OTC) device that emits energy in the blue and red spectrum for the treatment of mild to moderate inflammatory acne.

6. Comparison to Predicate Devices

Compare with the predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards.

Elements of Comparison	Subject device	Predicate device (K230720)	Reference device(K160691)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Light Tree Ventures Europe B.V.	Zuko, Inc.	--
Trade Name	LUSTRE GoGlow Advanced LED Patches	LUSTRE 3XPRESS Light Beauty Therapy patches	Acne Light Therapy Wand	--
Model	PR8001, PR9001	PR5001, PR6001	unknown	--
510 (K) Number	Applying	K230720	K160691	--
Product Code	OLP	OLP	OLP	Same
Regulation Class	Class II	Class II	Class II	Same
Indications for	LUSTRE GoGlow	The LUSTRE 3XPRESS	The Acne Light	Same

Elements of Comparison	Subject device	Predicate device (K230720)	Reference device(K160691)	Remark
Use / Intended use	Advanced LED Patches (Model: PR8001, PR9001) is an Over-the-Counter (OTC) device that emits energy in the blue and red spectrum for the treatment of mild to moderate inflammatory acne.	Light Beauty Therapy patches (Model: PR6001, PR5001) is an Overthe-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.	Therapy Wand is indicated to treat mild to moderate inflammatory acne.	
Power Source	Controller Lithium-ion Battery: 3.7Vdc, 200mAh, 0.74Wh	Input: 100-240Va.c., 50Hz/60Hz, output: DC 5V, 2A	1 AAA alkaline batteries	Different Note 1
Wavelengths	630 ± 10nm 415 ± 10nm	630 ± 10nm 415 ± 10nm	442 ± 4nm 633 ± 4nm	Same
Irradiance Source	LED	LED	LED	Same
LED Number	For each model: Blue: 12 Red: 12 Total: 24	For each model: Blue: 12 Red: 12 Total :24	unknown	Same
Intended Location Use	Face	Face	Face	Same
Irradiance (mW/cm^2)	Red: 5-8mW/cm^2 Blue: 23-27mW/cm^2 Total: 28-35mW/cm^2	Red: 5 Blue: 25 Total:30	Red:7.5 Blue:26.5 Total:34.0	Similar Note 2
Dose / per time(J/cm^2)	5.04-6.3	5.4	12.2	Similar Note 2
Treatment Time	3 minutes per treatment	3 minutes per treatment	unknown	Same
EMC	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	Same
Safety	IEC 60601-1 IEC 60601-2-83 IEC 60601-1-11 IEC 62471 IEC 60601-1-6	IEC60601-1 IEC60601-2-57 IEC60601-1-11 IEC62471	IEC60601-1 IEC62471	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 ISO 10993-11	ISO 10993-1 ISO10993-5 ISO10993-10 ISO 10993-23 ISO 10993-11	unknown	Same

Comparison in Detail(s):

Note 1: Although the power supply of the subject device differs slightly from the predicate device, they all comply with the safety requirements of IEC 60601-1, IEC 60601-1-2 and IEC 62133-2. Therefore, this minor difference does not raise any safety or effectiveness issues.

Note 2: The subject device's irradiance and dose/per time are slightly different from those of the predicate device and reference device, but they are very close. This minor difference does not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical testing was performed on the subject device to validate the design and ensure compliance with the following standards related to medical device electrical safety, electromagnetic compatibility, photobiological safety and battery safety:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015+AMD1:2020 Edition 2.1 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 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.
- 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 Acrylate Mini Dots of the LUSTRE GoGlow Advanced LED Patches (Model: PR8001, PR9001) in its final finished form is identical to Mini Dots of the predicate device, the "LUSTRE 3XPRESS Light Beauty Therapy patches(model: PR6001, PR5001)" in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The predicate device is manufactured by Shenzhen Kaiyan Medical Equipment Co., Ltd and was cleared under K230720, dated July 3, 2023. There is no change in biocompatibility since the previously cleared devices. Therefore, based on this information, no biocompatibility testing was needed to support substantial equivalence of this device.

3) Software Verification and Validation

Software verification and validation testing consistent with basic documentation were conducted in accordance with the recommendations provided in the FDA guidance document "Content of Premarket Submissions for Device Software Functions." The corresponding documentation has been provided.

4) Usability Validation

Usability testing was conducted on the LUSTRE GoGlow Advanced LED Patches (Models: PR8001, PR9001), 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 provides sufficient evidence to support that the device can be used safely and effectively.

8. Date Prepared: February 11, 2026

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as the legally marketed predicate device K230720 and K160691.