January 28, 2026

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

Re: K252603
Trade/Device Name: HIGHERDOSE Body Sculptor (Model: GS-03)
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: July 26, 2025
Received: August 18, 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.01.28 19:38:14 -05'00'

for 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)*
K252603

Device Name
HIGHERDOSE Body Sculptor (Model:GS-03)

Indications for Use *(Describe)*
The HIGHERDOSE BODY SCULPTOR (Model: GS-03) is an over-the-counter device that is intended to improve the appearance of 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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"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."

510(k) Summary

K252603

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

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: 0755-82129361

Fax: 0755-25024651

E-mail: alaindijkstra@kaiyanmedical.com

Distributor

Company Name: HIGHERDOSE LLC

Address: 42 Broadway, 12th Floor, #212, NewYork, NY 10004

Establishment Registration Number: 3019734322

Contact Person: Sumish Khadka

E-mail: sumish@higherdose.com

Manufacturer:

Manufacturer 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: 0755-82129361

Fax: 0755-25024651

E-mail: alaindijkstra@kaiyanmedical.com

2. Date of the summary prepared: January 27, 2026

3.Subject Device Information

Classification Name: Light Based Over-the-Counter Wrinkle Reduction (OHS)

Trade Name: HIGHERDOSE Body Sculptor (Model: GS-03)

Review Panel: General & Plastic Surgery

Product Code: OHS

Regulation Number: 878.4810

Regulatory Class: II

4. Predicate Device Information

Predicate Device 1 Information

Sponsor: Light Tree Ventures Europe B.V.

Trade Name: Infrared Heat, (Model: E0221)

Classification Name: Light Based Over The Counter Wrinkle Reduction

510(K) Number: K223893

Review Panel: General & Plastic Surgery

Product Code: OHS

Regulation Number: 878.4810

Regulation Class: II

Predicate Device 2 Information

Sponsor: Shenzhen Kaiyan Medical Equipment Co., Ltd

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

Classification Name: Light Based Over The Counter Wrinkle Reduction

510(K) Number: K250532

Review Panel: General & Plastic Surgery

Product Code: OHS

Regulation Number: 878.4810

Regulation Class: II

Predicate Device 3 Information

Sponsor: Dongguan Laiguang Electronic Technology Co.,Ltd.

Trade Name: Bestqool LED therapy device

Classification Name: Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne

510(K) Number: K242789

Review Panel: General & Plastic Surgery

Product Code: OHS, OLP

Regulation Number: 878.4810

Regulation Class: II

5. Device Description

The HIGHERDOSE Body Sculptor (Model: GS-03) is a home-use light-emitting diode phototherapy device with two proven wavelengths of light 650nm Red light and 850nm Near infrared red light, both of these lights are known to reducing the wrinkle.

The main device is made of black plastic (ABS+PC) and silicone button cup, and contain light emitting diode (LED) which will emit red light and infrared light. The device is a handheld device.

The device contains a rechargeable Lithium battery, which can be charged by charging disk. The HIGHERDOSE Body Sculptor cannot be operated while charging.

Press and hold the power button to turn the product on/off. Press the power button briefly to turn the LED light therapy on/off.

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.

6. Intended Use / Indications for Use

The HIGHERDOSE BODY SCULPTOR (Model: GS-03) is an over-the-counter device that is intended to improve the appearance of wrinkles.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device 1 K223893**	**Predicate Device 2 K250532**	**Predicate Device 3 K242789**	**Remark**
Company	Shenzhen Kaiyan Medical Equipment Co.,Ltd	Light Tree Ventures Europe B.V.	Shenzhen Kaiyan Medical Equipment Co.,Ltd	Dongguan Laiguang Electronic Technology Co.,Ltd.	--
Trade Name	HIGHERDOSE Body Sculptor	Infrared Heat (Model: E0221)	Solawave 2-in-1 Skincare Mini (61043)	Bestqool LED therapy device Model: LMK-001LMK-004LMK-005LMK-006	--
Classification Name	Light Based Over the Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction	Light Based Over the Counter Wrinkle Reduction, Over-The-Counter Powered Light-Based Laser for Acne	--
510(k) Number	K252603	K223893	K250532	K242789	--
Product Code	OHS	OHS	OHS	OHS, OLP	Same
FDA Device Classification	Class II	Class II	Class II	Class II	Same
Intended Use / Indications for Use	Light Therapy: The HIGHERDOSE BODY SCULPTOR (Model: GS-03) is an over-the-counter device that is intended to	The infrared Heat (Model:E0221) is intended to emit energy in the red and infrared spectrum for use in the treatment of full face	The Solawave 2-in-1 Skincare Mini (Model: 61043) is an over-the-counter device that emits energy in the	This device produces light in the blue light (415nm) is intended to reduce mild to moderate inflammatory acne	Same

	improve the appearance of wrinkles.	wrinkles.	red and infrared spectrum for treating wrinkles on the face and decolletage.	vulgaris. The red light (635nm) in combination with near-infrared light (850nm) is intended to improve the appearance of wrinkles.	
Intended Loaction Use	Body	Face	Face	Face and Body	
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Red: 650nm±10nm, Near-infrared :850nm±10nm	Red: 630nm±20nm Near-infrared :830±20nm	Red: 630nm ±10nm Near-infrared: 830nm ±10nm	Red :635nm±10nm Near-infrared :850nm±10nm	Similar Note 1
Total Intensity (mW/cm^2)	Red+Near-infrared : 650nm+850nm Total:40±10 mW/cm^2	Red+Near-infrared : 630nm + 830nm Total: 30mW/cm^2	Red+Near-infrared : 630nm+830nm Total: 40-55 mW/cm^2	Red+Near-infrared : 635nm+850nm Total: 7.5mW/cm^2 ± 25%	Similar Note 2
Treatment Time	10 mins	10 minutes per day, 2-5 times per week	3 minutes per treatment area	4 times a week 30-60 minutes session 4 weeks	Same
Software controller	Device uses a timer and software to control treatment duration and LED's intensity	Device uses a timer and software to control treatment duration and LED's intensity	Device uses a timer and software to control treatment duration and LED's intensity	Device uses a timer and software to control treatment duration	Same

Note1：

The subject device's wavelength is similar with the predicate devices 1, 2, 3 (K223893, K250532, K242789). The wavelengths of these lights are all within the spectral range of red and near-infrared light. Therefore, the subject device and predicate device provide the same treatment benefit.

Additionally, the subject device has already passed the testing regarding to standard IEC 60601-2-57 and LED material has passed IEC 62471 standards. In conclusion, the device is safe and effective. The slight differences between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note 2:

The subject device's intensity is similar with the predicate devices 1, 2 (K223893, K250532). The intensity of these lights are all within the spectral range of red and near-infrared light. Therefore, the subject device will not raise any safety or effectiveness issues.

The subject device is not higher than Predicate Device 2 (55mW/cm^2 , indicating the safety of the device, and no lower than Predicate Device 3(K242789) 7.5mW/cm^2 +/- ± 25%, indicating the effectiveness of the device. The subject device's intensity is between with rage of 3 Predicate Devices. Additionally, the subject device has already passed the testing regarding to standard IEC 60601-1 and IEC 60601-2-57. In conclusion, the device is safe and effective. The slight differences between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Final Conclusion:

The subject device is the same or similar to the legally marketed predicate device K223893, K250532, K242789.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary

HIGHERDOSE Body Sculptor (Model: GS-03) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/Significant Deviations	Test results
General requirements for basic safety and essential performance	IEC 60601-1:2005 /AMD1:2012/AMD 2:2020	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	IEC 60601-1-2:20 14+A1:2020	No degradation of performance was found during test or Lower than limits of measurement	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	IEC 60601-1-11:2 015/AMD1:2020	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
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- 2-57:2 011	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass

Title of the test	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/Significant Deviations	Test results
Photobiological safety of lamps and lamp systems.	IEC 62471:2006	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard. Purchase the products from the supplier, and the test is conducted by the supplier.	NA	Pass
Li-ion Battery safety	IEC 62133-2:2017	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard. Purchase the products from the supplier, and the test is conducted by the supplier.	NA	Pass
Performance Test	The Performance Test Report performs the following tests on the finished product: Power Density Test; Leakage current test.	The device can meet the requirement of the performance test, Power Density test and Leakage current test.	NA	Pass

2) Biocompatibility testing

The applied part of subject device, gel and spray will have direct contact with the human body.

The Biocompatibility testing was conducted on GS-03. The subject device complies with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-23 (Irritation).

3) Usability Testing

Usability testing was conducted on GS-03, the device complies with IEC 62366-1 and IEC 60601-1-6.

4) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff"

8.2 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.

9. Final Conclusion：

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K223893, K250532, K242789.

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