March 3, 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: K241947
Trade/Device Name: EnergyLounger (TY-01)
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, OLI, ILY
Dated: July 1, 2024
Received: July 3, 2024

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: 2025.03.03 17:11:12 -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)*
K241947

Device Name
EnergyLounger, model: TY-01

Indications for Use *(Describe)*
M1 is used to reduce the circumference of the hips, waist and thighs and is indicated for use as a noninvasive dermatological.
M2 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.
M3 is intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis, pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.

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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510(k) Summary for K241947

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
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Contact Person (including title): Alain Dijkstra (Manager)
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Application Correspondent:

Contact Person: Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com
Date Prepared: Febuary 10, 2025

2. Subject Device Information:

Trade Name: EnergyLounger, model: TY-01
Classification Name: Light based over the counter wrinkle reduction Lamp, Infrared, Therapeutic Heating Fat Reducing Low Level Laser
Review Panel: General & Plastic Surgery
Product Code: OHS, ILY, OLI
Regulation Number: 21 CFR 878.4810, 21 CFR 890.5500, 21CFR 878 5400
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K153399)

Sponsor: LED Intellectual Properties, LLC
Trade Name: LightStim Professional LED Bed
Classification Name: Infrared Lamp, Therapeutic Heating
Review Panel: Physical Medicine
Product Code: ILY
Regulation Number: 21 CFR 890.5500
Regulation Class: II

Predicate Device 2 (K232977)

Sponsor: Biophotas Inc
Trade Name: Biophotas Celluma CONTOUR
Classification Name: Light based over the counter wrinkle reduction
Review Panel: General & Plastic Surgery
Product Code: OLI, ILY, OHS

Regulation Number: 21 CFR 878.5400, 21 CFR 890.5500, 21 CFR 878.4810
Regulation Class: II

Predicate Device 3 (K223147)
Sponsor: MyBlend
Trade Name: MyLedMAsk
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 EnergyLounger, Model: TY-01 a device designed similar to a recliner, with 1260 LED lights, a switch for power on/off, and it can automatically stop treatment after 20 minutes use for M1/M2 and after 30 minutes use for M3, 2 buttons for mode selection, and an AC power supply for power supply.
The LED in the EnergyLounger, Model: TY-01 is a 1W imitation current light. It's a 4-in-1 LED, including 630nm, 630nm, 850nm and 940nm.The EnergyLounger, Model: TY-01 includes a detailed Instruction Manual, operators need to read the instructions carefully before use.
This device uses three types of LEDs and has three working modes, which can be selected by the user by pressing a button.
The device consists of an Energy Lounger, power cable, Product cover, Product protect cover, Reflector, Goggles and User Manual.

5. Intended Use / Indications for Use
M1 is used to reduce the circumference of the hips, waist and thighs and is indicated for use as a non-invasive dermatological.
M2 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.
M3 is intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis, pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.

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, material 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 (K153399)	Predicate device (K232977)	Predicate device (K223147)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	LED Intellectual Properties LLC	Biophotas Celluma CONTOUR	MyBlend	--

Elements of Comparison	Subject device	Predicate device (K153399)	Predicate device (K232977)	Predicate device (K223147)	Remark
Trade Name	EnergyLounger	LightStim Professional Led Bed	Biophotas Celluma CONTOUR	MyLedMAsk	--
Model	TY-01	N/A	N/A	N/A	--
510 (K) Number	K241947	K153399	K232977	K223147	--
Regulation Class	Class II	Class II	Class II	Class II	Same
Indications for Use / Intended use	M1 is used to reduce the circumference of the hips, waist and thighs and is indicated for use as a non-invasive dermatological. M2 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles. M3 is intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis. pain or muscle spasm, the temporary increase in local blood circulation, and the	The LightStim Professional LED Bed is an over-the-counter device intended to emit energy in the visible and IR spectrum intended to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.	The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red 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	MyLedMask is an over-thecounter device that is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles	Same

Elements of Comparison	Subject device	Predicate device (K153399)	Predicate device (K232977)	Predicate device (K223147)	Remark
	temporary relaxation of muscles.		relaxation of muscle tissue; and to temporarily increase local blood circulation. The BioPhotas Celluma CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.		
Power Source	Input: 100-240Vac 50/60Hz, 30.5 A/115Vac, 16A/230Vac Output: 12Vdc, 240A	Unpublished	90-264 VAC	Voltage: 100 to 240 volts, AC Frequency: 50-60Hz Intensity: 0.35 A	Different, note 1
Wavelengths	630nm, 850nm, 940nm	630nm, 660nm, 855nm, 940nm	Red: 640nm +/- 25nm 880nm +/- 50nm	Red: 630 nm (OSRAM LS T67F) NIR: 850 nm (OSRAM SFH 4253)	Similar, note 2
Irradiance source	LED	LED	LED	LED	Same
LED number	1260	18240	Unpublished	Total 288 LEDs - 144 for 630 nm and 144 for 850 nm - 244 for the face	Different note3

Elements of Comparison	Subject device	Predicate device (K153399)	Predicate device (K232977)	Predicate device (K223147)	Remark
				and 44 for the neck	
Intended location Use	Full body	Full body	Full body	Full Face and neck	Same
Irradiance (mW/cm^2)	M1 (630nm): 4.2 mw/cm^2 M2 (630nm+850nm): 18.7 mw/cm^2 M3 (630+850+940nm): 60 mw/cm^2	60 mW/cm 2	640nm - 4.2mW/cm 2 880nm - 0.7mW/cm2	18.7 mW/cm^2 (average of 6 measurement location (including one on the neck) between 10 to 27 mW/cm^2)	Same
LED distribution	Uniform distribution	Uniform distribution	Uniform distribution	Uniform distribution	Same
Treatment Time	M1: 20min M2: 20min M3: 30min	5-30 min	30min	According to skin phototype, daily - 1 fair skin: 5 min 35 (335 s) - 2 moderately dark skin: 11 min 10 (670 s) - 3 dark skin: 13 min 55 (835 s) during 6 to 8 weeks	Same

Comparison in Detail(s):

Note 1： Although the “Power Supply” is a little different from the predicate devices, they all complied with the IEC 60601-1, and IEC 60601-1-2 series safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

Note 2: Although the “Wavelengths” is a little different from the predicate devices, but wavelengths of the subject device can be covered by the predicate device. Due to the characteristics of LED lights, the

emission parameters are showing the peak wavelength of the lamp, and have been assessed by IEC 62471, So, these slight differences will not raise any safety or effectiveness issues.

Note 3: Although the “Number of LEDs” is different from the predicate devices, but the safety and performance are depend on the Irradiance, so the number of LEDs will 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 tests were performed on the subject device in order 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 - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
- 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 1.0 2011-01 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.

2) Biocompatibility Test

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (In Vitro Cytotoxicity), ISO 10993-10 (Skin Sensitization) and ISO 10993-23 (Irritation reactivity).

3) Usability validation

Usability testing was conducted on the EnergyLounger (Models: TY-01), 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 described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: February 10, 2025

9. <u>Final Conclusion</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devicesK153399, K223147 and K232977.