December 1, 2025

Shenzhen Suyzeko Limited.
Meng Liu
General manager
Room 301, Building N, No.17 Innovation Industrial Park
Xintian Community Guanhu Street, Longhua District
Shenzhen, Guangdong 518110
China

Re: K252786
Trade/Device Name: Led Light Phototherapy Bed (Pro 450/ GY-680A)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI, ILY
Dated: September 2, 2025
Received: September 2, 2025

Dear Meng Liu:

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: 2025.12.01 10:12:41 -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)*
K252786

Device Name
Led Light Phototherapy Bed (Pro 450/ GY-680A)

Indications for Use *(Describe)*
Led Light Phototherapy Bed is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
Led Light Phototherapy Bed is indicated to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, and pain and stiffness associated with arthritis, for promoting relaxation of the muscle tissue, and to temporarily increase local blood circulation.

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) #: K252786

510(k) Summary

Prepared on: 2025-12-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Suyzeko Limited.
Applicant Address	Room 301, Building N, No.17 Innovation Industrial Park, Xintian Community Guanhu Street, Longhua District Shenzhen Guangdong 518110 China
Applicant Contact Telephone	86-755-29500180
Applicant Contact	Mr. Meng Liu
Applicant Contact Email	jiang13620586569@126.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Led Light Phototherapy Bed (Pro 450/ GY-680A)
Common Name	Low level laser system for aesthetic use
Classification Name	Fat Reducing Low Level Laser
Regulation Number	878.5400
Product Code(s)	OLI, ILY , 21 CFR 890.5500

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202955	Contour Light CL-100	OLI
K153399	LightStim Professional Led Bed	ILY

Device Description Summary

21 CFR 807.92(a)(4)

LED phototherapy bed is a low-intensity LED light source (red and infrared LED) system that uses 630nm light to reduce the circumference of the hips, waist, and thighs for aesthetic benefits, and temporarily increases skin temperature using 630nm, 660nm, 855nm, and 940nm light.
The device consists of two LED panels, a software control console for selecting and maintaining LED light applications, a power adapter, and cables connected to the energy source. The LED panels can be adjusted to roughly fit the external dimensions of the patient being treated. The device is powered by connecting it to an 220-240V AC, at 4000VA, 50-60Hz power source.
The equipment is controlled by professional operators. The operator control device includes additional safety measures, including an emergency stop button. If activated, the emergency stop will stop the program and shut down, delivering power to the treated person through the LED light.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Led Light Phototherapy Bed is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
Led Light Phototherapy Bed is indicated to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, and pain and stiffness associated with arthritis, for promoting relaxation of the muscle tissue, and to temporarily increase local blood circulation.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same between proposed device and predicate device .

Technological Comparison

21 CFR 807.92(a)(6)

The wavelength of Slimming mode of the proposed device (630nm) is similar to the predicate K202955 (635nm); The wavelength of the pain relief mode of the proposed device is same as the predicates K153399 (630nm, 660nm, 855nm, and 940nm).

The Output Intensity/Irradiance of the Slimming mode of the proposed device (4.1 mW/cm2) is same to the predicates K202955; The Output Intensity/ Irradiance of the Pain relief mode of the proposed device (58-60 mW/cm2) is similar to the predicates K153399 (60 mW/cm2).

The treatment time (30 min) is the same as K202955 and within range of K153399. The structure of the proposed device is same to the predicate K153399.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests Submitted:
The following non-clinical testing was provided in this 510(k):
Electrical Safety and Electromagnetic Compatibility Testing – Led Light Phototherapy Bed has been tested and meets the following standard requirements of medical equipment:

- IEC60601-1: 2005+2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-57:2011 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.
- Photobiological Safety Testing – The Led Light Phototherapy Bed have been tested and comply with IEC 62471:2006, Photobiological safety of lamps and lamp systems, 1st edition. This IEC standard incorporates the principles of the following ANSI IESNA recommended practices.

Software Verification and Validation – Software documentation consistent with enhanced documentation level was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Equipment performance testing and verification– The LED Light Phototherapy Bed Pro 450/ GY-680Awere subjected to equipment performance testing (testing items include: Appearance, Effective irradiance, Timing and functions, Effective irradiation area, Effective red irradiance Uniformity, Safety test, Dielectric strength, Packaging inspection);
The device has passed all the tests mentioned above, and based on these test results, the manufacturer believes that the LED Light Phototherapy Bed Pro 450/ GY-680A are essentially equivalent to the device without causing new safety and effectiveness issues.

After analyzing non-clinical testing data, the intended use and supporting data can conclude that the device in the submission is substantially equivalent to the predicate device.