November 27, 2024

Shenzhen Walton Technology Co., Ltd.
℅ Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510530
China

Re: K242638
Trade/Device Name: LED Light Therapy Machine (G1, G3, G4, G6)
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: April 30, 2024
Received: September 3, 2024

Dear Cassie Lee:

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: 2024.11.27 15:14:48 -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)*
K242638

Device Name
LED Light Therapy Machine, model: G1, G3, G4, G6

Indications for Use *(Describe)*
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 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.

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

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 Walton Technology Co., Ltd.
Establishment Registration Number: 3029971459
Address: Room 801, Jiaxiye Plaza, No. 318 Minzhi Avenue, Minzhi Community, Minzhi Street, Longhua District, Shenzhen City, Guangdong Province
Contact Person (including title): Nidan Li (General Manager)
Tel: +86 0755-86963236
Fax: /
E-mail: linidan@relassy.com
Zip: 518131

Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86-20-8266-2446
Email: regulatory@glomed-info.com

2. Subject Device Information:

Trade Name: LED Light Therapy Machine, model: G1, G3, G4, G6
Classification Name: Light Based Over-The-Counter Wrinkle Reduction (OHS);
Over-The-Counter Powered Light Based Laser For Acne (OLP);
Lamp, Infrared, Therapeutic Heating (ILY)
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP, ILY
Regulation Number: 21 CFR 878.4810, 21 CFR 890.5500
Regulation Class: II

3. Predicate Device Information

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

4. Device Description

The LED Light Therapy Machine, Models: G1, G3, G4, G6, is an LED phototherapy device for over-the-counter (OTC) use. The device package includes the LED Light Therapy Machine, an electrical adaptor to power the device, eye safety goggles, and a user manual. The device will automatically stop the treatment after a preset time. The device contains LEDs that emit light at 460 nm (blue), 620 nm (red), and/or 850

nm (infrared). The device can emit blue light only, red light only, infrared only, or blue light plus red light plus infrared light simultaneously.

5. Intended Use / Indications for Use

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 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.

6. Comparison to predicate devices

Elements of Comparison	Subject device	Primary device (K223544)	Remark
Company	Shenzhen Walton Technology Co., Ltd.	Guangdong Newdermo Biotech Co., Ltd	--
Trade Name	LED Light Therapy Machine	LED light therapy mask	--
510 (K) Number	K242638	K223544	--
Product code	OHS, OLP, ILY	OHS, OLP, ILY	
Regulation Class	Class II	Class II	Same
Indications for Use / Intended use	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 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.	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 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.	Same
Regulation Number	21 CFR 878.4810, 21 CFR 890.5500	21 CFR 878.4810, 21 CFR 890.5500	Same
Regulation Name	Light Based Over The Counter Wrinkle Reduction (OHS), Over-The-Counter Powered Light Based Laser For Acne (OLP), Infrared, Therapeutic Heating (ILY)	Light Based Over The Counter Wrinkle Reduction (OHS), Over-The-Counter Powered Light Based Laser For Acne (OLP), Infrared, Therapeutic Heating (ILY)	Same
Regulatory Class	II	II	Same
Location for use	Face and body	Face and body	Same

Elements of Comparison	Subject device	Primary device (K223544)	Remark
Power Source	Input: 100-240 V~, 50/60Hz, 0.8 A Output: DC 12V, 2A	Input: 100-240 V~, 50/60Hz, 0.25 A Output: DC 5 V, 500 mA	Different, note 1
Light source	LED	LED	Same
Wavelengths	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Same
Irradiance (mW/cm^2)	Red light: 2.0~3.0 Blue light: 2.0~4.0 Infrared light: 2.0~4.0 Mixed light: 9.0~12.0	Red light: 2.0~3.0 Blue light: 2.0~4.0 Infrared light: 2.0~4.0 Mixed light: 9.0~12.0	Same
Treatment time	Manual Mode (Mode: M1, M2, M3, M4): 15 minutes each time; Automatic Mode (Mode C): 10 minutes each time. 3-4 treatment a week, reduce to 1-2	Manual Mode: 15 minutes each time; Automatic Mode: 10minutes each time. 3-4 treatment a week, reduce to 1-2	Same
Output Intensity (mW/cm^2)	Red light: 2.0~3.0 Blue light: 2.0~4.0 Infrared light: 2.0~4.0 Mixed light: 9.0~12.0	Red light: 2.0~3.0 Blue light: 2.0~4.0 Infrared light: 2.0~4.0 Mixed light: 9.0~12.0	Same

Comparison in Detail(s):

Note 1:

Although the electrical power adaptor for the proposed device has differences from the predicate device's electrical power adaptor, the proposed device conforms to the IEC 60601-1 and IEC 60601-1-2 performance standards and the differences are considered to be acceptable for this device.

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
- 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 LED Light Therapy Machine, Models G1, G3, G4, G6, is used in non-contact mode. The goggles conform to biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization) and ISO 10993-23 (Skin Irritation).

3) Software verification and validation
Software verification and validation testing were conducted and documentation was 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." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation
Usability testing was conducted on the LED Light Therapy Machine (Models: G1, G3, G4, G6), 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: November 25, 2024

9. Final Conclusion
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K223544.