March 3, 2026

Shenzhen Hanhua Opto Co., Ltd.
℅ Jun Da Huang
Project Manager
Registrar Corp.
Rm. 502, Bldg. A, Phase I, Qianhai Economic And Trade Center
151 Free Trade W. St., Nanshan Sub-District,Qianhai
Shenzhen, Guangdong Province 518066
China

Re: K253874
Trade/Device Name: LED Therapy Light (COB1400, HP1800PRO)
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, ILY
Dated: December 1, 2025
Received: December 4, 2025

Dear Jun Da Huang:

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: 2026.03.03 15:45:56 -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

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)*
K253874

Device Name
LED Therapy Light (COB1400, HP1800PRO)

Indications for Use *(Describe)*
The LED Therapy Light is an over-the-counter (OTC) device intended for the following uses:
For Red Mode: The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles.

For NIR Mode: The device is intended 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 relaxation of muscle tissue; and to temporarily increase local blood circulation.

For Red + NIR Mode: The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face 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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510(k) Summary - K253874

LED Therapy Light

Date of 510(k) Summary Preparation: 2025-12-01

1. Applicant Information

Shenzhen Hanhua Opto Co., Ltd.
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2. Submission Correspondent

Registrar Corp
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Contact Person: HUANG Jun Da Ken
Telephone Number: +86 137 6074 9097
Email: adnil1330@vip.qq.com

3. Proposed Device

Trade Name:	LED Therapy Light
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Infrared lamp.
Model(s):	COB1400, HP1800PRO
Classification Regulation Number:	21 CFR 878.4810 21 CFR 890.5500
Product Code:	OHS (Light Based Over The Counter Wrinkle Reduction) ILY (Lamp, Infrared, Therapeutic Heating)
Device Class:	II
FDA CDRH Review Panel:	General & Plastic Surgery Physical Medicine

4. Predicate Devices

Predicate Device #1:

510(k) Number:	K223544
Applicant:	Guangdong Newdermo Biotech Co.,Ltd
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Infrared lamp.

Trade Name:LED Light Therapy Mask (FM-01, FM-02, FM-03)

This predicate device has not been subject to a design-related recall.

Predicate Device #2:

510(k) Number:	K212275
Applicant:	Aesthetic Technology, Ltd.
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. Infrared lamp.
Trade Name:	Dermalux® Flex MD

This predicate device has not been subject to a design-related recall.

Predicate Device #3:

510(k) Number:	K171323
Applicant:	Biophotas, Inc.
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Trade Name:	Biophotas Celluma^3

This predicate device has not been subject to a design-related recall.

5. Device Description

The LED Therapy Light employs dual-spectrum LEDs that emit red and near-infrared light, allowing simultaneous delivery of both wavelengths for synergistic treatment effects.

6. Indications for Use

The LED Therapy Light is an over-the-counter (OTC) device intended for the following uses:

For Red Mode: The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles.

For NIR Mode: The device is intended 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 relaxation of muscle tissue; and to temporarily increase local blood circulation.

For Red + NIR Mode: The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face wrinkles.

7. Comparison to the Predicate/Reference Device(s)

Indications for Use/Intended Use:

The subject *LED Therapy Light* is an Over-the-Counter (OTC) device mainly intended for treatment of wrinkles, and providing topical heating for multiple purposes. All devices share the similar anatomical location and intended use for treatment. The proposed device can be used at home and healthcare settings.

Technological Characteristics:

The subject *LED Therapy Light* has the similar principle of operation and characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is as safe and effective as the predicate devices for its intended use.

The subject *LED Therapy Light* is substantially equivalent to the predicate devices in that it has the same/similar intended use and technological characteristics, as demonstrated in the following ***Table* 1 *Substantial Equivalence Comparison***.

Table 1 Substantial Equivalence Comparison

Feature	Proposed Device	Predicate Device #1 (K223544)	Predicate Device #2 (K212275)	Predicate Device #3 (K171323)	Remarks
Manufacturer	Shenzhen Hanhua Opto Co., Ltd.	Guangdong Newdermo Biotech Co.,Ltd	Aesthetic Technology, Ltd.	Biophotas, Inc.	/
Device Name	LED Therapy Light	LED Light Therapy Mask	Dermalux® Flex MD	Biophotas Celluma^3	/
Model(s)	COB1400, HP1800PRO	FM-01, FM-02, FM-03	Not Specified	Not Specified	/
Intended Use	The LED Therapy Light is an over-the-counter (OTC) device intended for the following uses: For Red Mode: The device emits energy in the red spectrum and is intended for the treatment of full-face wrinkles. For NIR Mode: The device is intended 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 relaxation of muscle tissue; and to temporarily increase local blood circulation. For Red + NIR Mode: The device emits energy in the red and infrared spectrum and is intended for the treatment of full-face wrinkles.	**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.	**Intended to deliver heat in the IR 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 relaxation of muscle tissue; and to temporarily increase local blood circulation.** The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. **Intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital and full face wrinkles.**	**The BioPhotas Celluma^3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.**	Same
Rx or OTC	OTC	OTC	OTC	OTC	Same
Product Code	OHS, ILY	OHS, OLP, ILY	OHS, OLP, ILY	OHS	Same
Light Source	LED	LED	LED	LED	Same
Anatomical Location	Face and Body	Face	Face and Body	Face	Same
Wavelength	**Red Light Mode:** 660 nm **NIR Mode:** 850 nm **Red＋NIR Mode:** 660 nm＋850 nm	**Red Light:** 620 nm **Infrared Light:** 850 nm **Mixed Light:** 460 nm, 620 nm, 850 nm	**Red Light:** 633 nm ± 5 nm **NIR Light:** 830 nm ± 5 nm	**Red:** 640 nm ± 25 nm **NIR:** 880 nm ± 50 nm	Same
Intensity / Irradiance	**COB1400 (～20 inches / 50 cm Distance):** **Red Light Mode:** 6.147 mW/cm^2 **NIR Mode:** 1.425 mW/cm^2 **Red＋NIR Mode:** 7.687 mW/cm^2 **HP1800PRO (～20 inches / 50 cm Distance):** **Red Light Mode:** 4.116 mW/cm^2 **NIR Mode:** 1.56 mW/cm^2 **Red＋NIR Mode:** 5.675 mW/cm^2	**Red:** 2.0～3.0 mW/cm^2 **Infrared:** 2.0～4.0 mW/cm^2 **Mixed:** 9.0～12.0 mW/cm^2	**Red Light:** 11.5 mW/cm^2 **NIR Light:** 5.5 mW/cm^2	6.5 mW/cm^2	Same *Within the range of the predicate devices*
Treatment Time	Maximum 30 min per session	**Manual Mode:** 15 minutes each time **Automatic Mode:** 10 minutes each time. 3～4 treatment a week, reduce to 1～2 treatment a week once the results shown.	Up to 30 Minutes	3 treatments per week (1800 Seconds) 4 weeks	Same *Within the range of the predicate devices*

8. Performance Data

The following performance data are provided in support of the substantial equivalence determination:

The proposed device performs testing in accordance with the following recognized consensus standards:

IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2:2014+AMD1:2020 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

IEC 60601-1-11:2015+AMD1:2020 Medical Electrical Equipment - Part 1-11: 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 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

IEC 62471:2006 Photobiological safety of lamps and lamp systems

IEC 60601-2-57:2023 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, cosmetic and aesthetic use

IEC 60601-2-83: 2019+AMD1:2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

IEC 62304:2006+AMD1:2015 Medical Device Software - Software Life Cycle Processes

Software verification and validation testing were conducted and basic level of documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions (2023)."

9. Clinical/Animal Testing

Clinical/animal testing was not performed for the proposed device as part of the submission.

10. Conclusions

Based on the above performance as documented in this application, the LED Therapy Light is found to have a safety and effectiveness profile that is similar to the predicate devices.