August 7, 2026

Shenzhen Chuangtong Yigou Technology Co., Ltd.
% Candice Qiu
Registration specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K261601
Trade/Device Name: LED Light Therapy Mask (M01, M02, M03, M05, M06, M07, M08)
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
Dated: May 14, 2026
Received: May 14, 2026

Dear Candice Qiu:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.08.07 13:51:12 -04'00'

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)*
K261601

Device Name
LED Light Therapy Mask (M01, M02, M03, M05, M06, M07, M08)

Indications for Use *(Describe)*
The LED Light Therapy Mask is an over-the-counter (OTC) device intended for the following uses:
For Red+NIR Mode: Treatment of full-face wrinkles.
For Blue+Red+NIR mode: 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

10(k) Summary #K261601

"510(k) Summary" as required by 21 CFR Part 807.92.

Date prepared: 2026-8-7

I. Submitter

Shenzhen Chuangtong Yigou Technology Co., Ltd
Room 2218, Rongchuang Zhihui Building A, Shangfen Community, Minzhi Street, Longhua District, Shenzhen, China
Kingway Hong
Manager
Tel: +86 13410362992
Email: kingway.hong@ctonetech.com

II. Device

Name of Device: LED Light Therapy Mask
Model(s): M01, M02, M03, M05, M06, M07, M08.
Regulation Name: Light Based Over The Counter Wrinkle Reduction; Over-The-Counter Powered Light Based For Acne
Regulatory Class: II
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810

III. Predicate Device and reference device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Walton Technology Co., Ltd.	LED Light Therapy Machine (Model: G1, G3, G4, G6)	K242638	November 27, 2024

Reference device:

Manufacturer	reference device	510(k) Number	Approval Date
Shenzhen Siken 3D Technology Development Co., Ltd.	LED light therapy mask (Model: SKB-2318L)	K243040	December 20, 2024

IV. Device Description

The subject device LED Therapy Mask is a home use wearable LED phototherapy device whose purpose is to produce an even and narrow-band of light for the treatment of aesthetic indications including facial wrinkles and acnes.

The subject device consists of a mask body unit that contains light emitting diodes (LEDs), a controller, straps and Charging cable. And the device is powered by built-in rechargeable lithium battery on the controller.

The LEDs generate 3 kinds of light mode which include Cleanse mode (Blue 460nm+Red 620nm+Infrared 850nm), Revitalize mode (Red 620nm+Infrared 850nm) and Stabilize mode(Blue 460nm+Red 620nm+Infrared 850nm). A controller is connect to the mask body unit to control the device, such as turn on/off the device, switch LED output. And the straps used for securing the mask unit to the face part.

V. Indications for Use

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

For Red+NIR Mode: Treatment of full-face wrinkles.
For Blue+Red+NIR mode: Treatment of mild to moderate inflammatory acne.

VI. Comparison of Technological Characteristics With the Predicate Device

The LED Light Therapy Mask has the same intended use, mode of action and similar operational characteristics as the predicate device. Any minor differences between the subject device and the listed predicate device and reference device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference device for its intended use. Therefore, the LED Light Therapy Mask may be found substantially equivalent to its predicate device and reference device.
LED Light Therapy Mask is compared with the following Predicate Device and reference device in terms of intended use, design, material, specifications, and performance:

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	K261601	K242638	K243040	/
Trade name	LED Light Therapy Mask	LED Light Therapy Machine	LED light therapy mask	/
Model	M01, M02, M03, M05, M06, M07, M08	G1, G3, G4, G6	SKB-2318L	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen Walton Technology Co., Ltd.	Shenzhen Siken 3D Technology Development Co., Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	Same
Classification Name	Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For Acne(OLP).	Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For	Light Based Over The Counter Wrinkle Reduction (OHS); Over-The-Counter Powered Light Based Laser For	Same

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	K261601	K242638	K243040	/
		Acne(OLP); Infrared,Therapeutic Heating(ILY)	Acne(OLP)	
Product code	OHS, OLP	OHS, OLP, ILY	OHS, OLP	Same
Device classification	Class II	Class II	Class II	Same
Indication for use/ Intended use	The LED Light Therapy Mask is an over-the-counter (OTC) device intended for the following uses: For Red+NIR Mode: Treatment of full-face wrinkles. For Blue+Red+NIR mode: 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.	LED Light Therapy Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Dimension	Approx. 337.5mm*231.22mm*8.52mm	Not publicly available	Model SKB-2318L : 411*195*4mm	Different

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	K261601	K242638	K243040	/
Power supply	DC 3.7V 1200 mAh Li-ion Battery	Input: 100-240 V~, 50/60Hz, 0.8A Output: DC 12V, 2A	Input: AC 100-240V 50-60Hz 0.3A Output: DC 5V 1A 3.7V 650mAh Li-ion Battery 3.7V1000mAh Li-ion Battery	Different
Sterilization	Not applicable	Not applicable	Not applicable	Same
Light source	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Same
Location for use	Face	Face and body	Face	Same
Wavelength	Blue: 460 nm±10nm Red: 620nm±10nm Near-Infrared: 850nm±10nm	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	SKB-2318L: Blue: 460nm±10nm Red: 620nm±10nm Infrared: 850nm±10nm	Same
Irradiance (mW/cm^2)	There are three modes: Cleanse mode: Blue+Red+Infrared: 9-12 mW/cm^2 Revitalize mode: Red+Infrared: 8-22 mW/cm^2 Stabilize mode: Blue+Red+Infrared: 9-12	Red light: 2.0~3.0 Blue light: 2.0~4.0 Infrared light: 2.0~4.0 Mixed light: 9.0~12.0	SKB-2318L: Mode 1: Red： 3.5~10mW/cm^2 Mode 2: Blue： 2.5~8mW/cm^2 Mode 3: Red+Infrared Light： 6~27mW/cm^2	Similar

Comparison Elements	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	K261601	K242638	K243040	/
	mW/cm^2 Error: ±20%			
Treatment time	20 minutes	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	It is recommended to use it for 10 minutes a day, 3 times per week.	Different
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-83; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471 IEC 62133-2	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5, ISO 10993-10 and ISO 10993-23	Same

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Evaluation

- The biocompatibility evaluation for the body-contacting components of the LED Light Therapy Mask was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recommended by FDA.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2: 2020, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility.
- IEC 60601-1: 2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .
- IEC 60601-1-11: 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 60601-2-83: 2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.

3) Eye Safety

- IEC 62471:2006, Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***Basic 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.

VIII. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LED Light Therapy Mask is as safe, as effective, and performs as well as the legally marketed predicate devices.