December 17, 2025

Shenzhen Goodwind Technology Development Co.,Ltd.
% Bing Huang
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518082
China

Re: K252983
Trade/Device Name: Wrinkle Retreat Pro Light Therapy Face Mask (Model: PH-m03)
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
Dated: September 18, 2025
Received: September 18, 2025

Dear Bing 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 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.12.17 16:03:25 -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)*
K252983

Device Name
Wrinkle Retreat Pro Light Therapy Face Mask (Model: PH-m03)

Indications for Use *(Describe)*
The Wrinkle Retreat Pro Light Therapy Face Mask is an Over-the-Counter (OTC) device intended for use in treating 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.

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."

510(k) Summary

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

K252983

Date: 2025-12-16

I. Submitter

Shenzhen Goodwind Technology Development Co.,Ltd.
Room 801, Building 1, Baolong Intelligent Manufacturing Park,No. 34,
Baotong Road, Baolong Community, Longgang District, Shenzhen, Guangdong, China.
Post code: 518116
Tel.: 86-755-28197384

Ziming Yang
General Manager
Tel.: +86-13802283843
Email:admin@goodwind.com.cn

Distributor:
Solawave Inc.
925 N La Brea Ave, Suite 400
Los Angeles, CA 90038 USA
www.mysolawave.com
@solawave

II. Device

Name of Device: Wrinkle Retreat Pro Light Therapy Face Mask (Model: PH-m03)
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHS
Regulation Number: 21 CFR 878.4810

III. Predicate Device

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Kaiyan Medical Equipment Co., Ltd	Q-Rejuvalight Pro Facewear (P19-0023)	K230042	April 28, 2023

Shenzhen Idea Light Limited	LED silicone mask (Model: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200)	K233114	January 12, 2024

Reference device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Kaiyan Medical Equipment Co., Ltd	LED Eye Mask(model: EY-20R, A20, EY-20N)	K233556	January 4, 2024

IV. Device Description

The Wrinkle Retreat Pro Light Therapy Face Mask (Model: PH-m03) adopts light emitting diodes (LED) in amber(605nm±5nm), red (630nm±5nm), red (660nm±5nm) and near-infrared (830nm±5nm) spectrum to irradiate on the face to realize its therapeutic effect. The Wrinkle Retreat Pro Light Therapy Face Mask adopts the form of a mask that contains LEDs on the inner surface of the main unit. A controller is connected to the main unit to control the device, such as to turn on/off the device. To use the device, user should place the mask over the face and use the controller to operate. The device will automatically turn off after each treatment. To prevent irradiation of LED lights to eyes during the treatment, this Mask has incorporated protective eye-shield which blocks light energy from LEDs.
The Mask is powered by a built-in rechargeable lithium battery which is located in the controller.

V. Indications for Use

The Wrinkle Retreat Pro Light Therapy Face Mask is an Over-the-Counter (OTC) device intended for use in treating full-face wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Device

Wrinkle Retreat Pro Light Therapy Face Mask is compared with the following Predicate Devices and Reference Device in terms of intended use, design, specifications, and performance:

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Reference Device**	**Remark**
510(k) Number	K252983	K230042	K233114	K233556	/
Trade name	Wrinkle Retreat Pro Light Therapy Face Mask(model:PH-m03)	Q-Rejuvalight Pro Facewear (P19-0023)	LED silicone mask (Model: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200)	LED Eye Mask(model: EY-20R, A20, EY-20N)	/
Manufacturer	Shenzhen Goodwind Technology Development Co.,Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd	Shenzhen Idea Light Limited	Shenzhen Kaiyan Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHS	OHS, OLP	OHS, OLP	OHS	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	The Wrinkle Retreat Pro Light Therapy Face Mask is an Over-the-Counter (OTC) device intended for use in treating full-face wrinkles.	The QRejuvalight ProFacewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate Inflammatory acne.	LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-thecounter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. LED silicone mask (Models: LP-RVTGLWP-WHT, LP-RVTGLW-WHT, TLM200) is an over-thecounter device intended to emit energy in the red and Near Infra-red	The LED Eye mask (Model: EY-20R, A20, EY-20N) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Reference Device**	**Remark**
			spectrum and is intended for the use in the treatment of full-face wrinkles.		
Location for use	Face	Face	Face	Periorbital region	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Power supply	Input: DC 5V/2A DC 3.7V 3600 mAh Li-ion Battery	Input: 5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	Rechargeable Lithium battery	Main unit: 3.7V, 300mAh lithium battery, 1.11Wh Adapter Input: 100 - 240Va.c., 50/60Hz Adapter	Similar **Note 1**
Light source	LEDs	LEDs	LEDs	LEDs	Same
Wavelength	Amber: 605 nm+/-5nm Red: 630 nm+/-5nm Red: 660 nm+/-5nm Near-Infrared: 830 nm+/-5nm	605nm, 630nm, 660nm, 880nm, 415nm	Red: 630nm±5nm Blue: 415nm NIR: 830nm	605nm, 633nm, 660nm, 830nm	Similar **Note 2**
LED Intensity (mW/cm^2)	Single wavelength: 605nm:25±20% mW/cm^2 630nm:14±20% mW/cm^2 660nm:18±20% mW/cm^2 830nm:8±20% mW/cm^2 Total: 65mW/cm^2	Single wavelength: 605nm: 15±5mW/cm^2 630nm: 20±5mW/cm^2 660nm: 25±5mW/cm^2 880nm: 10±5mW/cm^2 415nm: 25±5mW/cm^2 Total: 70mW/cm^2(wrinkle) 45mW/cm^2(acne)	Blue/Red 44 mw/cm^2 Red/NIR 30 mw/cm^2	605nm: 26.2±3 633nm: 13.8±3 660nm: 20.3±3 830nm: 8.5±3 Total: 65	Similar **Note 2**

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Reference Device**	**Remark**
Total Number of LEDs	320 pcs	80pcs	Red: 114 Blue: 114 NIR 114	605nm: 20 633nm: 20 660nm: 20 830nm: 20 Total: 40 (Double lamp beads)	Similar **Note 3**
LED Distribution	605nm+660nm(Double wick): 160 pcs 630nm+830nm(Double wick): 160 pcs	630nm+415nm (Double wick): 30pcs 630nm+605nm (Double wick): 25pcs 660nm+880nm (Double wick): 25pcs	Unknown	Uniform distribution	Similar **Note 4**
Treatment time	3 minutes	3 minutes per treatment	10 minutes/day	3 minutes	Same
Electrical safety	IEC 60601-1 IEC 60601-1- 11 IEC 60601-1-2 IEC 60601-2- 83 IEC 62133-2 IEC 62471	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 IEC 62471 IEC 60601-2-57	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 62133-2	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60601-2-57; IEC 62471	Same
Biocompatibility feature	ISO 10993-5, ISO10993-10, ISO 10993-23	ISO 10993-5, ISO10993-10, ISO 10993-23	ISO 10993-5, ISO10993-10, ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

VII. Performance Data

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

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the subject device were evaluated in biocompatibility evaluation in accordance with the FDA Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process'". The following testing was performed, and passed, including:

- ISO 10993-5: 2009, Biological evaluation of medical devices –Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and EMC Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, 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 60601-2-83:2022, Medical Electrical Equipment - Part 2-83: Particular Requirements For The Basic Safety And Essential Performance Of Home Light Therapy Equipment
- IEC 62133-2 Edition 5.0 2021-09, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.

3) Eye Safety

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

4) Software Verification and Validation

Software documentation consistent with ***basic level documentation*** 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.

Summary

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the subject device Wrinkle Retreat Pro Light Therapy Face Mask is to be concluded substantially equivalent to its predicate devices.