August 10, 2026

Shenzhen Goodwind Technology Development Co., Ltd.
Ziming Yang
Head of firm
Rm. 801, Bldg. 1, Baolong Intelligent Manufacturing Park, # 34, Baotong Rd., Baolong Ommunity,
Longgang District
Shenzhen, Guangdong 518116
China

Re: K261602
Trade/Device Name: Eye Recovery Pro (PH-e03)
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: May 14, 2026
Received: May 14, 2026

Dear Ziming Yang:

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: 2026.08.10 16:21:52 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261602

Please provide the device trade name(s).

Eye Recovery Pro (PH-e03)

Please provide your Indications for Use below.

The Eye Recovery Pro (PH-e03) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary - K261602

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

I. Submitter

Shenzhen Goodwind Technology Development CO., LTD
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Contact person: Ziming Yang
Title: General Manager
Title: Head of firm
Tel: +86 13802283843
E-mail: admin@goodwind.com.cn
Shenzhen Goodwind Technology Development CO., LTD
Date: 2026-05-14

II. Subject Device

Name of Device: Eye Recovery Pro
Model(s): PH-e03
Common or Usual Name: Light based over the counter wrinkle reduction
Regulation 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

510(k) number: K233556
Trade name: LED Eye Mask, model: EY-20R, A20, EY-20N
Product Codes: OHS
Classification: Class II
Regulation Number: 21 CFR 878.4810
Regulation Name: Light Based Over The Counter Wrinkle Reduction (OHS)
Manufacturer: Shenzhen Kaiyan Medical Equipment Co., Ltd

IV. Device Description

Eye Recovery Pro (PH-e03) is a home use wearable LED phototherapy device which can help reduce wrinkles within the periorbital region. Eye Recovery Pro is consisting of main unit (mask), Protective Eyewear (Detachable), Adjustable Head Straps, USB-C to USB-A Charging Cable, Storage Bag. There are 4 kinds of light, which include Amber light(wavelength 605nm), Red light (wavelength 630nm, 660nm) and Infrared light (wavelength 830nm).

V. Indications for Use

The Eye Recovery Pro (PH-e03) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

VI. Comparison of Technological Characteristics With the Predicate Device

The Eye Recovery Pro has the same intended use as the predicate device. The technological characteristics, features, specifications, materials are similar to the predicate device. Any minor differences between the subject device and the listed predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate devices for its intended use.

Therefore, the Eye Recovery Pro (PH-e03) may be found substantially equivalent to its predicate device.

Item	Subject device	Predicate device	Remark
510 (k) number	K261602	K233556	/
Trade name	Eye Recovery Pro (Model: PH-e03)	LED Eye Mask, model: EY-20R, A20, EY-20N	/
Manufacturer	Shenzhen Goodwind Technology Development CO., LTD	Shenzhen Kaiyan Medical Equipment Co., Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	Same
Regulation name	Light Based Over The Counter Wrinkle Reduction (OHS);	Light Based Over The Counter Wrinkle Reduction (OHS);	Same
Product code	OHS	OHS	Same
Class	Class II	Class II	Same
Indications for use/ Intended use	The Eye Recovery Pro (PH-e03) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	The LED Eye mask (Model: EY-20R, 20A, EY-20N) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.	Same
Location for use	Periorbital region	Periorbital region	Same
OTC or prescription	OTC	OTC	Same
Power supply	DC 5V, 1A Lithium battery 3.7V, 500 mAh	Main unit: 3.7V, 300mAh lithium battery, 1.11Wh Adapter Input: 100 - 240Va.c., 50/60Hz Adapter Output: 5Vd.c, 2A	**Note 1**

Item	Subject device	Predicate device	Remark
Light source	Light emitting diodes	LED	Same
LED array	80 (40 dual-core)	605nm: 20 633nm: 20 660nm: 20 830nm: 20 Total: 40 (Double lamp beads)	**Note 2**
Wavelength	605nm, 630nm, 660nm, 830nm	605nm, 630nm, 660nm, 830nm	Same
Irradiance(mW/cm²)	65	605nm: 26.2±3 633nm: 13.8±3 660nm: 20.3±3 830nm: 8.5±3 Total: 65	Same
Treatment time	3 minutes	3 minutes	Same
Dimensions (mm)	300 x 76 x 9.5mm	Not publicly available	**Note 3**
Weight	Mask: 110g (not including straps)	Not publicly available	**Note 3**
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	Same

Item	Subject device	Predicate device	Remark
Biocompatibility feature	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

Note 1:

The power supply for the subject device is a little different from the predicate device, however the lithium battery of the subject device has passed IEC 62133-2 test, so this difference should not raise any safety/effectiveness problems.

Note 2:

Though the LED array is different from the predicate device, the subject device adopts the dual core beads, actually the number of each type of light used in the subject product and the predicate device is the same, also the subject device has passed the IEC 62471 test, so this difference should not raise any safety and effectiveness problems.

Note 3:

Though the dimension and weight are different from the predicate device, this difference is insignificant and do not raise any safety or effectiveness problems.

VII.Performance Data

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the Eye Recovery Pro 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. The following testing was performed to, 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

- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2021, 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 verification and validation testing was conducted and basic documentation 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."

VIII. Conclusions

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