October 26, 2026

Shenzhen Bway Tech Co., Ltd.
% Qin Wang
RA Specialist
Flying Drug & Medical Compliance Service Co., Ltd.
Rm.1505, Zhenye International Business Center, Qianhai Rd.
Shenzhen, Guangdong 518051
China

Re: K262984
Trade/Device Name: Red & Near Infrared LED Light Phototherapy Face Mask (Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02)
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: August 26, 2026
Received: August 27, 2026

Dear Qin Wang:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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: 2026.10.26 22:21:38 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K262984

Device Name
Red & Near Infrared LED Light Phototherapy Face Mask
Model(s): Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02

Indications for Use *(Describe)*
Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01:
- Red light: Treatment of full-face wrinkles.
- Red+Infrared Light: Treatment of full-face wrinkles.
- Amber light: Treatment of full-face wrinkles.
- Blue light: Treatment of mild to moderate inflammatory acne.
- Blue+Infrared light: Treatment of mild to moderate inflammatory acne.

Models: Bway-E01, Bway-E02:
It is an Over-the-Counter light therapy medical device that is intended to treat wrinkles in the periorbital region (the area around the eye) via the combination of red and infrared light.

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.

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510(k) Summary - K262984

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

I. Submitter

Shenzhen Bway Tech Co., Ltd.
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Contact person: Xiuzhu Zhang
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Tel: +86 15013512962
E-mail: BW-buyer01@USbway.net
Date: October 20, 2026

II. Subject Device

Name of Device: Red & Near Infrared LED Light Phototherapy Face Mask
Model(s): Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02
510(K) number: K262984
Classification: II
Common Name: light based over the counter wrinkle reduction; over-the-counter powered light based laser for acne
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number: 878.4810
Product Code: OHS, OLP
Review Panel: General & Plastic Surgery

III. Predicate and Reference Device(s)

No.	510(K) number	Product code	Classification	Trade name
1	K251667	OHS, OLP	Class II	LED Light Therapy Mask Models: M01, M02, M06, M07, M08, M09
2	K251588	OHS, OLP, ILY	Class II	LED Light Therapy Mask Models: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910
3	K162489	OHS	Class II	RED Light Device
4	K241857	OHS, OLP, ILY	Class II	LED Light Therapy Device (Models: KFB290, KFB291, KFB265, KFB293

IV. Device Description

Red & Near Infrared LED Light Phototherapy Face Mask is a home use wearable LED phototherapy device which can help reduce wrinkles and mild to moderate acne. Red & Near Infrared LED Light Phototherapy Face Mask is consisting of main unit(mask), Eye protector, Mask Straps, Charging Cable, Storage Bag. There are 4 kinds of light, which include Blue light(wavelength 415nm), Amber light(wavelength 605nm), Red light (wavelength 630nm) and Infrared light (wavelength 850nm).

V. Intended Use

Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01:

Red light: Treatment of full-face wrinkles.

Red+Infrared Light: Treatment of full-face wrinkles.

Amber light: Treatment of full-face wrinkles.

Blue light: Treatment of mild to moderate inflammatory acne.

Blue+Infrared light: Treatment of mild to moderate inflammatory acne.

Models: Bway-E01, Bway-E02:

It is an Over-the-Counter light therapy medical device that is intended to treat wrinkles in the periorbital region (the area around the eye) via the combination of red and infrared light.

VI. Comparison of Technological Characteristics With the Predicate Device

The Red & Near Infrared LED Light Phototherapy Face Mask(Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02) have the same intended use as the predicate devices and reference device. The technological characteristics such as wavelength, irradiance, power supply, are similar to the predicate devices and reference device. Any minor differences between the subject device and the listed predicate devices and reference device do no raise any issues of safety or efficacy. Performance data supports that the device is same and as effective as the predicate devices and reference device for its intended use.

Therefore, The Red & Near Infrared LED Light Phototherapy Face Mask(Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02) may be found substantially equivalent to its predicate devices and reference device.

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	**/**
Trade name	Red & Near Infrared LED Light Phototherapy Face Mask Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01, Bway-E01, Bway-E02	LED Light Therapy Mask(Models: M01, M02, M06, M07, M08, M09)	LED Light Therapy Mask/ Model: FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910	RED Light Device	LED Light Therapy Device(Models: KFB290, KFB291)	/
Manufacturer	Shenzhen Bway Tech Co., Ltd.	Shenzhen Liyoutong Technology Co.,Ltd.	Shenzhen Fittop Health Technology Co., Ltd.	Zhongshan Bisen Plastic Electronic Products Co., Ltd.	Dongguan Boyuan Intelligent Technology Co.,Ltd	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810 21 CFR 890.5500	Same
Product code	OHS, OLP	OHS, OLP	OHS, OLP, ILY	OHS	OHS, OLP, ILY	Same
Device classification	Class II	Class II	Class II	Class II	Class II	Same
Indication for use	**Models: Bway-FM01, Bway-FM02, Bway-**	**M01, M02, M06, M07, M08:**	The LED Light Therapy Mask (Model: FCM902,	The RED Light Device is an OTC device indicated to	- Red light: Treatment of full-face wrinkles.	Same as primary

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	/
	FM03, Bway-FM05, Bway-FM06, Bway-FN01: Red light: Treatment of full-face wrinkles. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Blue+Infrared light: Treatment of mild to moderate inflammatory acne. **Models: Bway-E01, Bway-E02:** It is an Over-the-Counter light therapy medical device that is intended to	Red light: Treatment of full-face wrinkles. Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Blue light: Treatment of mild to moderate inflammatory acne. Mixed light: Treatment of mild to moderate inflammatory acne. **M09:** Red+Infrared Light: Treatment of full-face wrinkles. Amber light: Treatment of full-face wrinkles. Mixed light: Treatment of mild to moderate inflammatory acne.	FCM905, FCM906, FCM908, 11-001-RBMASK, FCM910) is an Over the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne. **FCM902, FCM905, FCM906, FCM908:** a. Red light: Treatment of full-face wrinkles. b. Blue+Infrared light: Treatment of mild to moderate inflammatory acne. a. Yellow+Infrared light: Treatment of full-face wrinkles.	emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	- 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. - Red+Infrared Light: Treatment of full-face wrinkles. - Amber light: Treatment of full-face wrinkles. - Blue light: Treatment of mild to moderate inflammatory acne. - Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.	predicate device K251667 and predicate device 1 - K251588 and predicate device 2 - K162489.

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	**/**
	treat wrinkles in the periorbital region (the area around the eye) via the combination of red and infrared light.					
Prescription/ OTC	OTC	OTC	OTC	OTC	OTC	Same
Software/Firm ware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Intended location of use	Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01: Face Models: Bway-E01, Bway-E02: Periorbital region	Face	Face	Periorbital region	Face	Same
Power supply	Lithiumbattery 3.7V, 3000mAh	Input: 5V 1A; Lithium ion battery 3.7V, 3000mAh	Input: 100 -240 V ~ 50 / 60 Hz	Adaptor:100~240V AC 50/60Hz	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A	Same as primary

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	/
			Li-ion Polymer Battery (FCM902, FCM905, FCM906, FCM908, 11-001-RBMASK): 2850mAh Li-ion Polymer Battery (FCM910): 1000mAh	Lithium battery: 2x3.7V	Lithium ion battery: 1300mAh	predicate device K251667 and the battery has passed the IEC 62133-2 test
Light source	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Same
Wavelength	415nm, 605nm, 630nm, 850nm	415nm, 605nm, 630nm, 850nm	630nm ± 5nm visible red light; 880nm ± 5nm non-visible red light; 415±5nm blue light; 590±5nm yellow light	Red: 633 ±5nm Infrared: 830 ±5nm	635nm ±5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	Same as primary predicate device K251667
Irradiance (mW/cm^2)	**Models: Bway-FM01, Bway-FM02, Bway-FM03, Bway-FM05, Bway-FM06, Bway-FN01:**	Red light: 25mW/cm^2 Red+IR Light: 30mW/cm^2 Amber light: 15mW/cm^2	**FCM902, FCM905, FCM906, FCM908:** 1) "R" (Red) (630nm): low: 25mW/cm^2	125 mW/cm^2 70 mW/cm^2 (633 nm); 55 mW/cm^2 (830nm)	Red: 25mW/cm^2; IR: 3mW/cm^2; Red+IR: 30mW/cm^2;	Similar The irradiance of Red light, Red+Infrared Light, Amber

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	/
	Red light: 15-23mW/cm^2 Red+Infrared Light: 20-28 mW/cm^2 Amber light:8-14mW/cm^2 Blue light:15-30mW/cm^2 Blue+Infrared Light: 20-35mW/cm^2 **Models: Bway-E01, Bway-E02:** Red light：15-23mW/cm^2 Red+Infrared light：20-28mW/cm^2	Blue light: 25mW/cm^2 Mixed light: 12mW/cm^2	medium: 35mW/cm^2 high: 40mW/cm^2 2) "Y+NIR"(Yellow+NIR) (590nm+880nm) : Yellow: low: 5mW/cm^2 medium: 7mW/cm^2 high: 10mW/cm^2 NIR:10mW/cm^2 3) "G"(Green) :(520nm) : low: 3mW/cm^2 medium: 4mW/cm^2 high: 5mW/cm^2 4) "B+NIR" ("Blue+NIR): (415nm+880nm) : Blue: low: 15mW/cm^2 medium: 20mW/cm^2 high: 25mW/cm^2 NIR:10mW/cm^2		Blue: 18mW/cm^2; Amber: 20mW/cm^2; Mixed light: 9mW/cm^2;	light and Blue light is similar with primary predicate device K251667, and the irradiance of Blue+Infrared Light is similar with predicate device K251588, and within the scope of predicate devices.

Comparison Elements	Subject Device	Primary Predicate device	Predicate device 1	Predicate device 2	Reference device	Remark
510(k) Number	**Pending**	**K251667**	**K251588**	**K162489**	**K241857**	**/**
Treatment time	5/10/15/20/30 min	5 and 10minutes	**FCM905, FCM906, FCM908:** 3 minutes for "Red", "Yellow+NIR", "Green", "Blue+NIR"	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time.(5-7 minutes on each treatment zone).	For red, blue and red+infrared: 10, 20, 30 minutes For infrared, amber light and mixed light: 10, 20 minutes.	Same as reference device

VII. Performance Data

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

1) Biocompatibility Testing

All body-contacting materials are in contact with intact skin only and are included in Attachment G, Section B of the FDA Biocompatibility Guidance (Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process'); therefore, biocompatibility testing is not required. Furthermore, the Material Safety Data Sheet (MSDS) and justification for the color additive are disclosed.

2) Electrical Safety

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 CSV 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 60601-1-11:2015+AMD1:2020 CSV 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+AMD1:2022 CSV Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62133-2:2017+AMD1:2021 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 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 is as safe, as effective, and performs as well as the legally marketed predicate devices.