October 11, 2024

Dongguan Boyuan Intelligent Technology Co., Ltd.
% Jilan Luo
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong Province 518052
China

Re: K241857
Trade/Device Name: LED Light Therapy Device (KFB290, KFB291, KFB265, KFB293)
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, ILY
Dated: June 26, 2024
Received: June 27, 2024

Dear Jilan Luo:

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: 2024.10.11 15:27:56 -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)*
K241857

Device Name
LED Light Therapy Device(Model(s): KFB290, KFB291, KFB265, KFB293)

Indications for Use *(Describe)*
KFB290, KFB291:

Red light: Treatment of full-face 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.

KFB265, KFB293:

Red+Infrared Light: Treatment of wrinkles.

Blue light: Treatment of mild to moderate inflammatory acne.

Amber light: Treatment of 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.

510(k) Summary

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

I. Submitter

Company name: Dongguan Boyuan Intelligent Technology Co.,Ltd
Address: Room 801, Building 3, No.3 Kuiqiao Road, Puxin Lake, Tangxia Town, Dongguan, Guangdong, China.

Contact person: Le Li
Title: Deputy general manager
Tel: +86-177 2259 0830
E-mail: 978953150@qq.com
Preparation date: September 24, 2024

II. Subject Device

Name of Device: LED Light Therapy Device
Model(s): KFB290, KFB291, KFB 265, KFB 293
Common or Usual Name: Light based over the counter wrinkle reduction
Over-The-Counter Powered Light Based Laser For Acne
Lamp, Infrared, Therapeutic Heating
Regulation Name:
Laser surgical instrument for use in general and plastic surgery and in dermatology
Infrared lamp.
Regulatory Class: II
Product Code: OHS, OLP, ILY
Regulation Number: 878.4810, 890.5500

III. Predicate and reference Devices

For KFB290, KFB291:

No.	Manufacturer	Device name	Product code	510(k) Number
1.	Guangdong Newdermo Biotech Co.,Ltd	LED light therapy mask	OHS, OLP, ILY	K223544
2.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	LED Facial Mask	OHS, OLP	K230351
3.	Zhongshan Bisen Plastic Electronic Products Co., Ltd.	RED Light Device	OHS	K162489

For KFB 265, KFB 293:

No.	Manufacturer	Device name	Product code	510(k) Number
1.	Hunan Guangye Biotechnology Co., Ltd.	Beauty LED Mask	OHS, OLP	K221151
2.	Shenzhen Kaiyan Medical Equipment Co., Ltd.	LED Facial Mask	OHS, OLP	K230351

IV. Device Description

KFB290, KFB291:

LED Light Therapy Device(Models: KFB290, KFB291) is a home use wearable LED phototherapy device which can help reduce wrinkles and acne and provide topical heating. LED Light Therapy Device is consisting of main unit(mask), controller, Silicone eye protector, USB charging cable and straps. The LED Light Therapy Device have 4 kinds of light, which include Red light (wavelength 635nm ± 5nm), Blue light (wavelength 465 ± 5nm), Infrared light (wavelength 850nm ± 5nm), Amber light (wavelength 605 ± 5nm).

KFB 265, KFB 293:

LED Light Therapy Device(Models: KFB 265, KFB 293) is a home use wearable LED phototherapy device which can help reduce wrinkles and acne and provide topical heating. LED Light Therapy Device is consisting of main unit(mask), controller, USB charging cable and adapter. There are several kinds of light having medical effects: Red + Infrared (wavelength 637nm and 854nm (± 5nm), Blue light (wavelength 465nm), Amber light (wavelength 605 ± 5nm).

V. Indications for Use

KFB290, KFB291:

a. Red light: Treatment of full-face wrinkles.
b. 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.
c. Red+Infrared Light: Treatment of full-face wrinkles.
d. Amber light: Treatment of full-face wrinkles.
e. Blue light: Treatment of mild to moderate inflammatory acne.
f. Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.

KFB265, KFB293:

a. Red+Infrared Light: Treatment of wrinkles.
b. Blue light: Treatment of mild to moderate inflammatory acne.
c. Amber light: Treatment of wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Device

The LED Light Therapy Device has the same intended use as the predicates. The technological characteristics, features, specifications, materials are similar to 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 safe and as effective as the predicate devices for its intended use.

Therefore, the LED Light Therapy Device may be found substantially equivalent to its predicate devices.

Table1: Substantial Equivalence Comparison for KFB290, KFB291

Comparison Elements	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) Number	Pending	K223544	K230351	K162489
Trade name	LED Light Therapy Device(Models: KFB290, KFB291)	LED light therapy mask, Models: FM-01, FM-02, FM-03	LED Facial Mask, Model(s): MZ-01, NEWKEY-01, SP-FM-01	RED Light Device
Manufacturer	Dongguan Boyuan Intelligent Technology Co.,Ltd	Guangdong Newdermo Biotech Co.,Ltd	Shenzhen Kaiyan Medical Equipment Co., Ltd.	Zhongshan Bisen Plastic Electronic Products Co., Ltd.
Regulation number	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle and Acne Reduction	Light Based Over The Counter Wrinkle Reduction
Product code	OHS, OLP, ILY	OHS, OLP, ILY	OHS, OLP	OHS
Device classification	Class II	Class II	Class II	Class II
Indication for use/ Intended use	- Red light: Treatment of full-face 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.	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 Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

	- Mixed light(Red+Blue +Infrared): Treatment of mild to moderate inflammatory acne.			
Prescription or OTC	OTC	OTC	OTC	OTC
Dimension	**KFB290:** Approximately 302 mm x 197 mm x 22 mm **KFB291:** Approximately 412 mm x 195 mm x 22 mm	**FM-01:** 207 * 277 * 43 mm, **FM-02:** 198 * 383 * 33.5 mm, **FM-03:** 237.5 * 108 * 8.1 mm	/	/
Power supply	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	Input: 100-240V, 50/60Hz, 0.25 A Output: DC 5 V, 500 mA	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V
Sterilization	Not applicable	Not applicable	Not applicable	Not applicable
Light source	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes
Location for use	Face	Face and body	Face	Face
Wavelength	635nm ± 5nm visible red light; 850nm±5nm Invisible red light; 465±5nm blue light; 605±5nm amber light	Red: 620nm Blue: 460nm Infrared: 850nm Mixed: 620nm and 850nm and 460nm	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm	Red: 633nm ±5nm visible red light; Infrared: 830nm±5nm Invisible red light;
Irradiance	Red: 25mW/cm^2; IR: 3mW/cm^2; Red+IR: 30mW/cm^2; Blue: 18mW/cm^2; Amber: 20mW/cm^2; Mixed light: 9mW/cm^2;	Red light: 2.0~3.0mW/cm^2 Blue light: 2.0~4.0mW/cm^2 Infrared light: 2.0~4.0 mW/cm^2 Mixed light: 9.0~12.0 mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber: 15~42mW/cm^2	125 mW/cm^2 70 mW/cm^2 (633 nm) 55 mW/cm^2 (830 nm)
Treatment time	For red, blue and red+infrared: 10, 20, 30 minutes For infrared, amber light and mixed light: 10, 20 minutes.	**Manual Mode:** 15 minutes each time, **Automatic Mode:** 10 minutes each time.	10 minutes/day, 3 times per week	15-20 minutes
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	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471

Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10	ISO 10993-1

Table2: Substantial Equivalence Comparison for KFB265, KFB293

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**
510(k) Number	Pending	K221151	K230351
Trade name	LED Light Therapy Device(Models: KFB 265, KFB 293)	Beauty LED Mask, Model: KFB 265	LED Facial Mask, Model(s): MZ-01, NEWKEY-01, SP-FM-01
Manufacturer	Dongguan Boyuan Intelligent Technology Co.,Ltd	Hunan Guangye Biotechnology Co., Ltd.	Shenzhen Kaiyan Medical Equipment Co., Ltd.
Regulation number	21 CFR 878.4810 21 CFR 890.5500	21 CFR 878.4810	21 CFR 878.4810
Classification Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP), Infrared Therapeutic Heating(ILY)	Light Based Over The Counter Wrinkle and Acne Reduction	Light Based Over The Counter Wrinkle and Acne Reduction
Product code	OHS, OLP, ILY	OHS, OLP	OHS, OLP
Device classification	Class II	Class II	Class II
Indication for use/ Intended use	- Red+Infrared Light: Treatment of wrinkles. - Blue light: Treatment of mild to moderate inflammatory acne. - Amber light: Treatment of wrinkles.	The device is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	LED Facial Mask is an over the counter device that is intended to use LED light for the treatment of wrinkles and mild to moderate acne.
Prescription or OTC	OTC	OTC	OTC
Dimension	**KFB 265:** Approximately 183 mm x 238 mm x 98 mm **KFB 293:** Approximately 228.3 mm x 139.5 mm x 90 mm **Controller:** 100mm x 50 mm x 21.5 mm	**LED Mask:** Approximately 183 * 238 * 98 mm **Controller:** 100 * 50 * 21.5 mm	/
Power supply	Input: 100 -240 V, 50 / 60 Hz Output: 5V, 1A Lithium ion battery: 1300mAh	Input: 100 -240 V ~ 50 /60 Hz Output: 5V 1A	An external adapter Input: AC 100-240V 50-60Hz 0.2A Output: DC 12V 0.5A

Comparison Elements	Subject Device	Predicate Device	Reference Device 1
510(k) Number	Pending	K221151	K230351
Sterilization	Not applicable	Not applicable	Not applicable
Light source	Light Emitting Diodes	Light Emitting Diodes	Light Emitting Diodes
Location for use	Face	Face	Face
Wavelength	visible red light: 637nm ± 5nm; invisible red light: 854nm ± 5nm; blue light: 465±5nm; amber light: 605±5nm;	Red (637nm±5nm) and IR (854nm±5nm); Blue (465±5nm)	Blue: 465nm±5nm Red: 625nm±5nm Amber: 605nm±5nm
Irradiance	Red+IR: 25.5mW/cm^2 Blue: 1.36mW/cm^2 Amber: 20mW/cm^2	Red+IR: 25.5mW/cm^2 Blue: 1.36mW/cm^2	Blue: 15~63mW/cm^2 Red: 31~75mW/cm^2 Amber: 15~42mW/cm^2
Treatment time	10 minutes	10 min	10 minutes/day, 3 times per week
Compliance with voluntary standards	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	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57 IEC62471
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10

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 LED Light Therapy Device 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 recognized 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: 2005+A1:2012+A2:2020 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014+A1:2020 - 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+A1:2020 - 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+A1:2022 - Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 60601-2-57: 2011 - 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 and cosmetic/aesthetic use
- IEC 62133-2: 2017, 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 ***moderate level*** of concern 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.