January 30, 2026

Shenzhen Jianchao Intelligent Technology Co., Ltd.
℅ Riley Chen
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90
Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K253833
Trade/Device Name: Facial & Body Beauty Device (model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507)
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, NFO
Dated: December 1, 2025
Received: December 1, 2025

Dear Riley Chen:

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: 2026.01.30 16:16:39 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253833

Device Name
Facial & Body Beauty Device (model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507)

Indications for Use *(Describe)*
Model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808:
Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.
(1) The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.
(2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.
Model: INIA-ED001, INIA-ED002, INIA-BLD001, E1507:
Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.
(1) The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation;
(2) The Photon mode: The red light is intended for the treatment of periorbital 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 - K253833

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

I. Submitter

Shenzhen Jianchao Intelligent Technology Co., Ltd.
Rm101, 201, 301, Bldg.25, No.68 Hexiu West Road, Fuhai St., Baoan, Shenzhen, Guangdong, 518107, CHINA
Fax: +86-0755-86961489

Fred Li
Title: Director
Tel.: +86 18675507170
Email: fred@vellcolife.com

Date of preparation: 2026-1-13

II. Device Information

Name of Device: Facial & Body Beauty Device
Models: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, INIA-ED001, INIA-ED002, INIA-BLD001, E1507
Common or Usual Name: Light Based Over The Counter Wrinkle Reduction
Over-The-Counter Powered Light Based Laser For Acne
Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: OHS, OLP, NFO
Regulation Number: 21 CFR 878.4810, 21 CFR 882.5890

III. Predicate Device & Reference Device

Predicate device:

Predicate Device	Manufacturer	510(k) Number	Product code
Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	Shenzhen Aozemei Technology Co. Ltd	K241718	OHS, OLP
2 Face / Face Evolution	Heat In A Click	K171821	NFO, OHS, OLP
Infrared Red Blue LED Light Heat Beauty Machine Model: Vega; Jupiter; Neptune	Marci Beauty Inc	K210545	OHS, OLP

Reference device:

Reference Device	Manufacturer	510(k) Number	Product code
Facial & Body Beauty Device	Shenzhen Jianchao Intelligent Technology Co., Ltd.	K252553	NFO

IV. Device Description

Facial & Body Beauty Device is portable, non-sterile and reusable device, which is designed to achieve the aesthetic effect. The device mainly consists of a main unit and charging cable, and it is supplied by internal rechargeable lithium battery, which can be recharged by external charger through the provided charging cable, but the device can not be used when charging.

The device is for home environment use, which has electrodes for microcurrent stimulation (the microcurrent stimulation mode was cleared under K252553) and light emitting diodes for light therapy treatment. Especially, the light therapy function of the device equips both red light (for wrinkles treatment) and blue light (for acne treatment) for model INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808, while equips only red light for model INIA-ED001, INIA-ED002, INIA-BLD001, E1507.

To use the device, user should place the treatment head on the face and body (only applicable for microcurrent stimulation mode). The device will automatically shut down after treatment time is over.

V. Indications for Use

Model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808:

Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.

(1) The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation.

(2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.

Model: INIA-ED001, INIA-ED002, INIA-BLD001, E1507:

Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes.

(1) The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation;

(2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles.

VI. Comparison of Technological Characteristics With the Predicate Device

The Facial & Body Beauty Device has the same intended use as the predicate devices. The technological characteristics, features, specifications, design and intended use are similar to the predicate devices. 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 safe and as effective as the predicate devices for its intended use.

Comparison Elements	**Subject Device**		**Predicate device 1**	**Predicate device 2**	**Predicate device 3**	**Remark**
K number	**K253833**		**K241718**	**K171821**	**K210545**	**/**
Trade name/ Model	Facial & Body Beauty Device, Model: INIA-BD001, INIA-BD002, INIA-BD003, INIA-BD004, F2C15, F3222 Pro, F5516, F3606, F2210 Pro, F5808	Facial & Body Beauty Device, Model: INIA-ED001, INIA-ED002, INIA-BLD001, E1507	Micro-current Facial Beauty Device Model: AM-810B, AM-810W, AM-812B, AM-812W	2 Face / Face Evolution	Infrared Red Blue LED Light Heat Beauty Machine Model: Vega; Jupiter; Neptune	/
Product code	OHS, OLP, NFO	OHS	OHS, OLP	NFO, OHS, OLP	OHS, OLP	Same
Indication for use/Intended use	Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes. (1) The Microcurrent st imulation mode is indic ated for facial skin stimulation and body skin stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	Facial & Body Beauty Device is a hand-held device for over-the counter aesthetic purposes. (1) The Microcurrent stimulation mode is indicated for facial skin stimulation and body skin stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles.	Micro-current Facial Beauty Device is intended for the treatment of facial wrinkles, and mild to moderate inflammatory acne.	2 Face / Face Evolution is a hand-held device for over-the counter aesthetic purposes. (1) The EMS mode is indicated for facial stimulation; (2) The Photon mode: The red light is intended for the treatment of periorbital wrinkles and the blue light is intended for the treatment of the mild to moderate inflammatory acne.	The Infrared Red Blue LED Light Heat Beauty Machine is an hand-held over-the-counter phototherapy device, the red and infrared light is intended for the use in treating wrinkles on the face and the blue light is intended for the treatment of the mild to moderate inflammatory acne. This device is indicated for adults only	Same (The microcurrent stimulation mode of the subject device was cleared under K252553)
OTC or prescription	OTC	OTC	OTC	OTC	OTC	Same

Comparison Elements	**Subject Device**		**Predicate device 1**	**Predicate device 2**	**Predicate device 3**	**Remark**
K number	**K253833**		**K241718**	**K171821**	**K210545**	/
Treatment site	Face	Face	Face	Entire face	Entire Face	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Power Supply	Internal Li-ion battery: 3.7Vd.c. 1100mAh	Internal Li-ion battery: 3.7Vd.c. 300mAh	Adapter input: 5V 0.5A Internal lithium battery: 3.7V/600mAh	DC 3.7V 2200mAh	900mAh, Rechargeable Li-Ion batteries	Different
Handheld design	Yes	Yes	Yes	Yes	Yes	Same as predicate
Energy type	Light emitting diodes (LEDs)	Light emitting diodes (LEDs)	Light emitting diodes	Light emitting diodes	LEDs	Same
Wavelength	Blue: 470nm ± 10nm Red: 630nm ± 10nm	Red: 630nm ± 10nm	415±10nm blue light 605±10nm amber light 630±10nm red light	Red: 630±3nm, Blue: 415±3nm	Blue: 465nm Red: 620-630nm IR: 845-855nm	Same
Intensity (mW/cm^2)	Blue: 4.48mW/cm² Red:2.3mW/cm²	Red:1.22mW/cm²	Red light: 2.5mW/cm^2 Amber light: 15mW/cm^2 Blue light: 1.4mW/cm^2	Red: 73.26 mW/cm^2±10%; Blue: 64.10 mW/cm^2±10%	Blue Light Mode: 5.4mW/cm^2 Red Light Mode: 7.2mW/cm^2	Similar
Main Materials	PC, PC+ABS, Zinc alloy	PC, ABS, Stainless Steel, Zinc alloy, Silica gel	ABS, PC	ABS Plastic & Stainless Steel	ABS Plastic and Aluminum Head	Different, but solved by biocompatibility test

Comparison Elements	**Subject Device**		**Predicate device 1**	**Predicate device 2**	**Predicate device 3**	**Remark**
K number	**K253833**		**K241718**	**K171821**	**K210545**	**/**
Dimensions	52(L)×48(W)×188 (H)mm	164.5(L)×31(W)×17.3 (H) mm	Not provided publicly	158mm*56mm*51.5mm	Not provided publicly	Different
Net Weight	220g	95.3g	Not provided publicly	200g	265g	Different

VII. Non-Clinical Testing

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

1) 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 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 62471:2006 Photobiological safety of lamps and lamp systems
- 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

2) Biocompatibility Testing

- 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

3) Software Verification and Validation

Software documentation consistent with ***Basic Documentation*** 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. Clinical Testing

Not applicable.

IX. 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.