August 10, 2026

Shenzhen Jianchao Intelligent Technology Co., Ltd.
% Renne Qin
Primary Contact
Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Rm. 1509, Jingting Bldg., Dongzhou Community, Guangming St., Guangming District
Shenzhen, Guangdong 518107
China

Re: K261705
Trade/Device Name: Hair Removal Device (R3C16-G Pro, R3C16-V Pro)
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: OHT
Dated: July 14, 2026
Received: July 14, 2026

Dear Renne Qin:

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 17:05:53 -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)*
K261705

Device Name
Name of Device: Hair Removal Device
Model(s): R3C16-G Pro, R3C16-V Pro

Indications for Use *(Describe)*
Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.

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.

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K261705

510(k) Summary

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

I. Submitter

Shenzhen Jianchao Intelligent Technology Co., Ltd.
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Contact person:Renne Qin
Title:RA Specialist
Date of preparation: July 24, 2026

II. Subject Device

Name of Device: Hair Removal Device
Model(s): R3C16-G Pro, R3C16-V Pro
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHT
Regulation Number: 21 CFR 878.4810

III. Predicate Device

Predicate device:

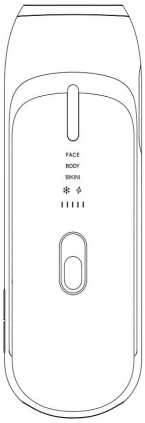
Predicate Device	Manufacturer	510(k) Number	Product code
Hair Removal Device (R3C16-P, R3C16-W, R3C16-G, R3C16-P Pro, R3C16-W Pro, R3C16-G Pro, R3505-W, R3505-B, R3505-W Pro, R3505-B Pro)	Shenzhen Jianchao Intelligent Technology Co.,Ltd.	K242710	OHT
IPL Hair Removal Device(JM-843, JM-865, JM-638)	Shenzhen Junmei Technology Co., Ltd.	K241881	OHT

IV. Device Description

Hair Removal Device (Model: R3C16-G Pro, R3C16-V Pro), is an over-the-counter, home-use and personal device for hair reduction based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

Hair Removal Device includes two models with identical intended use, performance and operation, consisting of IPL main unit and power adapter, which the main unit is mainly composed of lamp tube, filter, display screen, buttons, thermoelectric cooler, fan, and DC socket.

The device is only powered by the external power adapter. The device is fitted with a skin sensor to detect appropriate skin contact, if the treatment window of the device is not in full contact with the skin, the device cannot emit light pulses, and the IPL emission activation is by manual finger switch or auto light emission. All models of the Hair Removal Device have a cooling function for a better hair removal experience. The difference of design between models are listed below:

Model (s)	Enclosure color	Cooling function	Product drawing
R3C16-G Pro	Golden	Sapphire cooling	
R3C16-V Pro	Purple	Sapphire cooling	

V. Indications for Use

Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.

Comparison of Indications for Use: The indications for use of the subject device is comparable to the indications for use of the predicate device.

VI. Comparison of Technological Characteristics With the Predicate Device

The Hair Removal Device has the same indications for use, mode of action and similar operational characteristics as 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 Hair Removal Device may be found substantially equivalent to its predicate devices.

Hair Removal Device is compared with the following predicate devices and reference devices in terms of intended use, design, specifications and performance:

Item	Subject Device	Predicated device 1	Predicated device 2
510(k) number	K261705	K242710	K241881
Trade name	Hair Removal Device	Hair Removal Device	IPL Hair Removal Device
Model(s)	R3C16-G Pro, R3C16-V Pro	R3C16-P, R3C16-W, R3C16-G, R3C16-P Pro, R3C16-W Pro, R3C16-G Pro, R3505-W, R3505-B, R3505-W Pro, R3505-B Pro	JM-843, JM-865, JM-638
Manufacturer	Shenzhen Jianchao Intelligent Technology Co.,Ltd.	Shenzhen Jianchao Intelligent Technology Co.,Ltd.	Shenzhen Junmei Technology Co., Ltd.
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product code	OHT	OHT	OHT
Device classification	Class II	Class II	Class II
Indication for use/Intended use	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair
Prescription or OTC	OTC	OTC	OTC
Treatment area	Small areas such as underarm and facial hair below the chin	Small areas such as underarm and facial hair below the chin line, large	Information not available in 510(K)

	line, large areas such as arms and legs	areas such as arms and legs	summary
Applicable skin tone	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V
Source energy	An external power supply	An external power supply	An external power adaptor
Power supply	100~240V, 50/60Hz	100~240V, 50/60Hz	100~240V, 50/60Hz
Dimension(mm)	184.4*65.4*43.9mm	R3C16 series: 185*70*40mm R3505 series: 198*117*51mm	JM-843,JM-865:194*91*55 mm JM-638:132*80*52 mm
Sterilization	Not required	Not required	Not required
Light source	Intense Pulse Light	Intense Pulse Light	Intense Pulse Light
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc lamp
Wavelength range	530~1200nm	530~1200nm	JM-843,JM-865:530~1200nm JM-638:500~1200nm
Energy density	**R3C16-G Pro, R3C16-V Pro:** 1.4J/cm²~3.85J/cm²	**R3C16-P, R3C16-W, R3C16-G:** 1.56J/cm²~4.69J/cm² **R3C16-P Pro, R3C16-W Pro, R3C16-G Pro:** 1.39J/cm²~4.17J/cm² **R3505-W, R3505-B:**	JM-843,JM-865:1.94~5.45 J/cm^2 JM-638:.1.20~4.00J/cm^2

		3.57J/cm²~7.5J/cm² **R3505-W Pro, R3505-B Pro:** 3.03J/cm²~6.36J/cm²	
Spot size	3.9±0.25cm²	**R3C16-P, R3C16-W, R3C16-G:** 3.2±0.25cm² **R3C16-P Pro, R3C16-W Pro, R3C16-G Pro:** 3.6±0.25cm² **R3505-W, R3505-B:** 2.8±0.25cm² **R3505-W Pro, R3505-B Pro:** 3.3±0.25cm²	JM-843,JM-865:3.3cm²±0.25cm² JM-638:3.0cm²±0.25cm²
Pulse duration	6-11ms	R3C16 series: 6-11ms R3505 series: 11-12ms	JM-843,JM-865:10.2±1ms JM-638:9.0±1ms
Pulsing control	Finger switch	Finger switch	Finger switch
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Information not available in 510(K) summary

Output intensity level	5 levels	9 levels	1-5 levels
Software/Firmware /Microprocessor control?	Yes	Yes	Yes
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	EC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83
Eye safety	IEC 62471	IEC 62471	IEC 62471
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23

VII. Non-Clinical Testing

Non-clinical testing have been conducted to verify that the subject device meets all design specifications which supports the conclusion that it's substantially equivalent to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- 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
- 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: 2022, 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

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 device.