



December 6, 2024

Shenzhen Jianchao Intelligent Technology Co., Ltd.  
% Riley Chen  
RA Engineer  
Feiyong Drug & Medical Consulting Technical Service Group  
Rm 2401 Zhenye International Business Center, No. 3101-90  
Qianhai Road  
Shenzhen, Guangdong 518052  
China

Re: K242710

Trade/Device Name: 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)

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: September 5, 2024

Received: September 9, 2024

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yan Fu -S

Digitally signed by Yan Fu

-S

Date: 2024.12.06 13:50:30

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for 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

510(k) Number (if known)

K242710

Device Name

Name of Device: Hair Removal Device

Model(s): 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

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.

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# 510(k) Summary: K242710

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

## I. Submitter

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Date of preparation: 2024-09-06

## II. Device

Name of Device: Hair Removal Device  
Model(s): 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  
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 & Reference Device

Predicate device:

<u>Predicate Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>	<u>Product code</u>
Hair Removal Device (R2815-G Pro, R2815-G)	Shenzhen Jianchao Intelligent Technology Co., Ltd.	K232575	OHT
Ipulse Smoothskin Gold Hair Removal Device	Cyden Limited	K160968	OHT, GEX
IPL Hair Removal Device	SHENZHEN BORRIA TECHNOLOGY CO., LTD.	K232939	OHT

Reference device:



<u>Reference Device</u>	<u>Manufacturer</u>	<u>510(k) Number</u>	<u>Product code</u>
IPL Hair Removal Device Joy Version (CB-027)	Shen Zhen CosBeauty Co., Ltd	K173813	OHT
iPulse Hair Removal System	CyDen, Ltd.	K130315	OHT

#### IV. Device Description

Hair Removal Device (Model: 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), 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 series (R3C16 series and R3505 series) with a total of 10 models. The two series products adopt identical intended use, similar performance and operation, consisting of IPL host and power adapter, which the host 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, but the main difference is that the model with “Pro” in the model name is equipped with sapphire while the model without “Pro” uses metal treatment window surface. The difference of design between models are listed below:

Model (s)	Enclosure color	Cooling function	Product drawing
R3C16-P	Purple	Metal cooling	
R3C16-W	White	Metal cooling	
R3C16-G	Golden	Metal cooling	
R3C16-P Pro	Purple	Sapphire cooling	
R3C16-W Pro	White	Sapphire cooling	
R3C16-G Pro	Golden	Sapphire cooling	
R3505-W	White	Metal cooling	
R3505-B	Black	Metal cooling	
R3505-W Pro	White	Sapphire cooling	
R3505-B Pro	Black	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:

<b>Comparison Elements</b>	<b>Subject Device</b>	<b>Predicate Device 1</b>	<b>Predicate Device 2</b>	<b>Predicate device 3</b>	<b>Reference Device 1</b>	<b>Reference Device 2</b>	<b>Remark</b>
510(k) Number	K242710	K232575	K160968	K232939	K173813	K130315	/
Trade name	Hair Removal Device	Hair Removal Device	iPulse SmoothSkin Gold Hair Removal System	IPL Hair Removal Device	IPL Hair Removal Device Joy Version	iPulse Hair Removal System	/
Model (s)	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	R2815-G Pro, R2815-G	/	BR223, BR225	CB-027	/	/
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 iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse Smoothskin Gold is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	The IPL Hair Removal Device is indicated for the removal for unwanted hair. The IPL Hair Removal Device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of the treatment regime.	The IPL Hair Removal Device Joy Version is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults with Fitzpatrick skin types I - IV.	The iPulse Hair Removal System is an Over-the-counter device intended for the removal of unwanted hair.	Same
Prescription or OTC	OTC	OTC	OTC	OTC	OTC	OTC	Same
<b>Device design</b>							
Source energy	An external power supply	An external power supply	External Power supply	External Power supply	Supplied by external adapter	Supplied by external power converter	Same
Power supply	100~240V, 50/60Hz	100~240V, 50/60Hz	110V or 230V, 50/60Hz	Not public	100~240V, 50/60Hz	Not public	Same
Dimension (mm)	R3C16 series: 185*70*40mm R3505 series: 198*117*51mm	194*117*45mm	Not public	Not public	126*78*200mm	Not public	<u>Different</u>
Sterilization	Not required	Not required	Not required	Not required	Not required	Not public	Same
<b>Output specification</b>							

<u>Comparison Elements</u>	<u>Subject Device</u>	<u>Predicate Device 1</u>	<u>Predicate Device 2</u>	<u>Predicate device 3</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	530~1200nm	530-1200nm	510-1100nm	510~1100nm	510-1200nm	530-1100nm	Same
Energy density	<b>R3C16-P, R3C16-W, R3C16-G:</b> 1.56J/cm <sup>2</sup> ~4.69J/cm <sup>2</sup> ; <b>R3C16-P Pro, R3C16-W Pro, R3C16-G Pro:</b> 1.39J/cm <sup>2</sup> ~4.17J/cm <sup>2</sup> <b>R3505-W, R3505-B:</b> 3.57J/cm <sup>2</sup> ~7.5J/cm <sup>2</sup> ; <b>R3505-W Pro, R3505-B Pro:</b> 3.03J/cm <sup>2</sup> ~6.36J/cm <sup>2</sup>	Max. 5.2J/cm <sup>2</sup> (range 1.2J/cm <sup>2</sup> ~5.2J/cm <sup>2</sup> )	in 3-6J/cm <sup>2</sup>	Max.6.0J/cm <sup>2</sup>	1.8~5.1J/cm <sup>2</sup>	7-10J/cm <sup>2</sup>	Similar
Spot size	<b>R3C16-P, R3C16-W, R3C16-G:</b> 3.2±0.25cm <sup>2</sup> <b>R3C16-P Pro, R3C16-W Pro, R3C16-G Pro:</b> 3.6±0.25cm <sup>2</sup> <b>R3505-W, R3505-B:</b> 2.8±0.25cm <sup>2</sup> ; <b>R3505-W Pro, R3505-B Pro:</b> 3.3±0.25cm <sup>2</sup>	3.4±0.25 cm <sup>2</sup>	3cm <sup>2</sup> (3cm by 1cm)	3.36cm <sup>2</sup>	Body: 4.2cm <sup>2</sup> Bikini and face: 2.0cm <sup>2</sup>	3cm <sup>2</sup> (1.3cm by 2.4 cm)	Similar
Pulse duration	R3C16 series: 6-11ms R3505 series: 11~12ms	8.5±2.5ms (range in 6ms~11ms)	2ms to 10ms	8~12ms	9.2~11.2ms	Variable - Single pulse: 25ms Double Pulse: 20ms on, 60ms off.	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct Illumination To Tissue	Same
Output intensity level	9 levels	9 levels	Not public	Not public	5 levels	Not public	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Not public	Same

## VII. Non-Clinical Testing

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

- ISO 10993-5: 2009, Biological evaluation of medical devices –Part 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
- IEC 60601-1-6: 2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

## 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.