Shenzhen Rainbow Technology Co., Ltd.
% Cassie Lee
General Manager
Share Info (Guangzhou) Medical Consultant , Ltd.
1919-1920, Bldg. D3, Minjie Plz., Shuixi Rd.
Huangpu District
Guangzhou, Guangdong
China

Re: K263313
Trade/Device Name: Red Light Therapy Hair Growth Cap (RB-009, RB-011, RB-012, RB-088, RB-089, RB-092)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 21, 2026
Received: September 21, 2026

Dear Cassie Lee:

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: 2026.10.28 14:44:52 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263313

Please provide the device trade name(s).

Red Light Therapy Hair Growth Cap (RB-009, RB-011, RB-012, RB-088, RB-089, RB-092)

Please provide your Indications for Use below.

The Red Light Therapy Hair Growth Cap is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

Please select the types of uses.	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) Summary

K263313

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

1. Submitter's Information

Sponsor Name: Shenzhen Rainbow Technology Co., Ltd

Address: 3th Floor, No.2, Dongwangyang Industry, Huangtian Community, Hangcheng Street, Bao'an District, Shenzhen City, Guangdong province, China 518000

Contact name: Terry Liu (General Manager)

Tel: +86 137 6038 9092

Fax: /

E-mail: terry@rainbowdo.com

Application Correspondent:

Contact Name: Cassie Lee

Company: Share Info (Guangzhou) Medical Consultant Ltd.

Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China

Tel: +86 20 8200 6973

E-mail: 382198657@qq.com

2. Subject Device Information:

Type of 510(k): Traditional

Trade Name: Red Light Therapy Hair Growth Cap

Model: RB-009, RB-011, RB-012, RB-088, RB-089, RB-092

Review Panel: General & Plastic Surgery

Regulation number: 21 CFR 890.5500

Product Code: OAP

Regulatory Class: II

3. Predicate Device Information

Predicate Device

Sponsor: Shenzhen Kaiyan Medical Equipment Co., Ltd

Trade Name: Aduro Hair Growth; Trudermal Halo Hair growth system

Model Name:M-130, M-300;M-180A

510(k) Number: K253669

Medical specialty: Physical Medicine

Review Panel: General & Plastic Surgery

Regulation number: 21 CFR 890.5500

Product Code: OAP

Regulatory class: Class II

Reference Device

Sponsor: Zdeer Technology (Henan) Co., Ltd

Trade Name: Laser hair growth device

510(k) Number: K260899

Review Panel: General & Plastic Surgery

Regulation number: 21 CFR 890.5500

Product Code: OAP

Regulatory Class: II

4. Device Description

The Red Light Therapy Hair Growth Cap is a portable, non-invasive, battery-powered, head-mounted light therapy device intended to deliver optical energy to the scalp for the promotion of hair growth.

The device is available in six models: RB-009, RB-011, RB-012, RB-088, RB-089, and RB-092. Depending on the model, the device is provided in either a fabric baseball-cap configuration or a rigid plastic helmet-style configuration.

Each model consists of a cap assembly incorporating an optical source array, an integrated control module, a built-in rechargeable lithium-ion battery, and a USB charging cable. The optical source array is positioned on the inner surface of the cap to provide distributed light exposure over the intended treatment area of the scalp.

Depending on the model, the optical sources consist of red light-emitting diodes (LEDs), 660 nm laser emitters, or a combination of these optical sources.

The device operates using its built-in rechargeable lithium-ion battery. At the end of the preset treatment session, the device automatically stops operation.

Operating Principle

When the device is correctly positioned on the head and treatment is initiated, the optical source array directs light toward the scalp. The distributed arrangement of the optical sources provides coverage of the intended scalp treatment area without requiring the user to manually move the device during treatment.

Models RB-009, RB-011, and RB-012 are operated using a power/intensity button and a mode-selection button. The power/intensity button is used to turn the device on or off and select the available intensity setting. The mode-selection button is used to select the applicable operating mode.

Models RB-088, RB-089, and RB-092 are operated using a power button and incorporate a weight-sensing wear-detection function. The weight sensor detects the load applied when the cap is placed on the user’s head and controls device operation accordingly.

The available treatment modes and intensity settings vary by model and are described in the Operating Instructions. The device automatically shuts down when the preset treatment duration has elapsed.

5. Indications for Use

The Red Light Therapy Hair Growth Cap is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

6. Comparison to Predicate Devices

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Reference Device 1	Remark
Company	Shenzhen Rainbow Technology Co., td	Shenzhen Kaiyan Medical Equipment Co,. Ltd	Zdeer Technology (Henan) Co., Ltd	--
Trade Name	Red Light Therapy Hair Growth Cap	Aduro Hari Growth, Trudermal Halo Hair growth system	Laser hair growth device	--
Classification Name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	Same
510(k) Number	TBD	K253669	K260899	--
Product Code	OAP	OAP	OAP	Same

Intended use / Indications for Use	The Red Light Therapy Hair Growth Cap is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	The device are indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	The device is indicated to treat androgenetic alopecia for men and women. It is designed to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV.	Same
OTC or Rx	OTC	OTC	OTC	Same
Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Not public	Same
Energy Type	**RB-009**: Light emitting diodes **RB-011:** Light emitting diodes + LLLT **RB-012:** Light emitting diodes + LLLT **RB-088:** Light emitting diodes + LLLT **RB-089**: Laser diodes **RB-092:** Light emitting diodes + LLLT	M-130,M-180A: Light emitting diodes M-300: Light emitting diodes + LLLT	Laser diodes	Same
Wavelength of laser and LLLT	**RB-009:** Red 660nm +laser 660 nm **RB-011**: Red 660nm +laser 660 nm **RB-012:** Red 660nm +laser 660 nm **RB-088:** Red 660nm +laser 660 nm **RB-089**: Laser 660 nm **RB-092:** Red 660nm +laser 660 nm	M-130, M-180A: Red 660nm M-300: Red+laser 650 nm +/-5nm	Laser 650±20nm	Similar Note 1
Amounts of laser and LLLT Lamp	**RB-009**: 108 Red LEDS **RB-011, RB-012**: 90 Red LEDS +18 Laser **RB-088, RB-092**: 98	M-130: 130 Red LEDS M-180A: 180 Red LEDS M-300: 200 Red	88,120, 160, 200, 240, 280, 320, 360, 400	Similar Note 2

	Red LEDS +56 Laser **RB-089:** 154 Laser	LEDS +100 Laser		
Irradiance (mW/cm²)	＜5 mW/cm²	＜5 mW/cm²	＜5 mW/cm²	Same
Dose (J/cm²)	＜6.00 J/cm² ±5%.	M-130, M-180A:3J/cm² M-300: 7.5J/cm²	F21151~5: 7.80J/cm², 7.81J/cm², 7.68J/cm², 7.75J/cm², 7.66J/cm², F21156~9: 3.09J/cm², 3.18J/cm², 3.23J/cm² 3.12J/cm²,	Similar Note 3
Classification according to IEC60825-1	Class 1	No publicly available	Class 3R	Similar Note 4
Treatment Time	For model RB-009, RB-011, RB-012: Adjust among 10/15/20 minutes For model RB-088, RB-089, RB-092: 20 minutes	M-130, M-180A:10 minutes M-300: 25 minutes	16 weeks, for 30/12-minute treatment times	Similar Note 5
Treatment frequency	every other day, for 16 weeks	every other day, for 16 weeks	16 weeks, 3 times per week spaced out every other day	Same

7. Comparison in Detail(s):

Note 1:

Although the subject device is slightly different from the predicate device in terms of "**Wavelength of laser and LLLT**" , these parameters remain very close to those of the predicate device and reference device. These minor differences do not raise any issues of safety and effectiveness.

Note 2:

Although the subject device is slightly different from the predicate device in terms of "**Amounts of Laser Lamp**", these parameters remain very close to those of the predicate device and reference device. In addition, the wavelengths and Irradiance values are all close to the predicate device and reference device.

So, the minor differences do not raise any issues of safety and effectiveness.

Note3:

Although there are differences in the "**Dose (J/cm²)** between the Subject device and the Primary Predicate Device and Reference Device, the dose of subject device is similar to predicate device and reference device, the difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note4:

Although the subject device's "**laser classification**" (per IEC 60825-1) differs from that of the predicate device, it has undergone safety testing in accordance with IEC 60825-1 standards, and all test results comply with safety requirements. Therefore, this difference does not raise any safety or effectiveness concerns.

Note5:

Although the subject device's "**Treatment Time**" differs from that of the Subject device and the Predicate Device and Reference Devices, the Subject device is similar treatment durations compared to the duration of the Primary Predicate Device and Reference Device 1.

And all of the conducted the electrical and electromagnetic compatibility safety tests by following the IEC 60601 series and IEC 62471 standards, the test results demonstrate the device meet the IEC 60601 series IEC 62471 standards' requirements. Therefore, these differences do not raise concerns about safety or efficacy.

Final Conclusion:

This difference does not raise different risks or concerns of safety and effectiveness compared to the predicate. The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices.

8. Test Summary

8.1 Non-Clinical Tests Performed

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- 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 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-2-83:2019/AMD1:2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.
- IEC 62133-2 Edition 1.0 2017-02 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
- IEC 62471: 2006 First edition Photobiological safety of lamps and lamp systems.
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements

Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Basic Documentation level", since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Moderate Injury.

Cybersecurity

The subject device no any external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no need cybersecurity evaluation.

8.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9. Final Conclusion

This difference does not raise different risks or concerns of safety and effectiveness compared to the predicate. The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices.

10. Date of the summary prepared: September 20, 2026