June 5, 2025

Shenzhen Idea Light Limited
Nicole Liu
Manager
3rd Floor, Block B, Shengdelan Industry Park,
Longhua District
Shenzhen, Guangdong 518110
China

Re: K250467
Trade/Device Name: Red Light Hair Growth Cap (LP-RJVGRW-BLK)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP,
Dated: May 13, 2025
Received: May 14, 2025

Dear Nicole Liu:

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: 2025.06.05 14:55:53 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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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.

Submission Number *(if known)*

K250467

Device Name

Red Light Hair Growth Cap (LP-RJVGRW-BLK)

Indications for Use *(Describe)*

The Red Light 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.

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.

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510(k) Summary of K250467

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 Idea Light Limited
Establishment Registration Number: 3015287734
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Contact Person (including title): Nicole Liu (Manager)
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E-mail: Nicole@szidealight.com

Application Correspondent:

Application Correspondent:
Contact Person: Nicole Liu
Shenzhen Idea Light Limited
Address: 3rd Floor, Block B, Shengdelan Industry Park, Guanlan, Longhua District Shenzhen Guangdong, CN 518110
Tel: +86 0755 21055894
E-mail: Nicole@szidealight.com

2. Subject Device Information

Trade Name: Red Light Hair Growth Cap
Model: LP-RJVGRW-BLK
Regulation: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP

3. Primary Predicate Device Information

Sponsor: Light Tree Ventures Europe B.V.
Trade Name: CurrentBody Skin™ Led Hair Regrowth(Model: MZ-07)
Regulation: 21 CFR 890.5500

510(k) Number: K230336

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: OAP

Predicate Device 2 information:

Sponsor: Biophotas, Inc.

Trade Name: Biophotas Celluma RESTORE

Regulation: 21 CFR 890.5500

510(k) Number: K211038

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: OAP

4. Device Description

The Red Light Hair Growth Cap is an over the counter (OTC) home-use, non-invasive device 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 Red Light Hair Growth Cap is a portable, therapeutic device whose purpose is to provide even, cool, narrow-band wavelengths of polychromatic light (660nm red light) produced by LEDs to treat androgenetic alopecia and promote hair grown.

The device comprises of a wearable soft textile cap, a controller, an AC adaptor and a USB cable. The device can be powered by the AC adaptor which connected to the mains directly, also it can be powered by a power bank. The device is operated by the controller. There are 2 buttons on controller, ON/Off button is used to turn on/off the device, time button is used for setting treatment time from 10 to 30 minutes, each press in 5-minute increments./decrements. The device will shut off automatically after reach treatment time.

5. Intended Use / Indications for Use

The Red Light 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. Test Summary

6.1 Summary of Non-Clinical Performance Testing

Performance Testing Summary

The Red Light Hair Growth Cap (Model: LP-RJVGRW-BLK) has been thoroughly evaluated for electrical safety and performance and has been found to conform to the following standards.

1) Electrical safety and electromagnetic compatibility (EMC)

- 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
- 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 60601-2-57:2011 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 62471:2006 Photobiological safety of lamps and lamp systems.

2) 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 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 Minor Injury.

6.2 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.

7. Comparison to predicate device and conclusion

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

Elements of Comparison	Subject Device	Primary Predicate Device	Reference device	Verdict
Company	Shenzhen Idea Light Limited	Light Tree Ventures Europe B.V.	Biophotas Inc	--
Trade Name	Red Light Hair Growth Cap	CurrentBody Skin™ Led Hair Regrowth(Model: MZ-07)	Biophotas Celluma RESTORE	--
510(k) Number	K250467	K230336	K211038	--
Product Code	OAP	OAP	OAP	Same
Device classification	Class II	Class II	Class II	Same
Regulation number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Intended Use and Indications.	The Red Light 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 CurrentBody Skin™ Led Hair Regrowth(Model: MZ-07) 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 BioPhotas Celluma RESTORE 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.	Same
Intended location of use	Scalp	Scalp	Scalp	Same
Energy type	Light emitting diodes	Visible red light-emitting diodes	Light emitting diodes	Same
Peak Wavelength (FWHM)	Red: 660 nm	660nm	Red: 640nm+/-25nm (615-665nm)	Same
Intensity (mw/cm^2)	1.63	1.67	2.77	Similar Note 1
Treatment Dose (J/cm^2)	0.98-2.94	1	4.98	Similar Note 1
Treatment time	Every day 10-30 minutes.	Every day 10 mins	Each Treatment: 30 minutes; Total treatment: every other day, 16	Same Note 2

Elements of Comparison	Subject Device	Primary Predicate Device	Reference device	Verdict
			weeks	
Control	Device uses a timer and software to control treatment duration	Not public available.	Device uses a timer and software to control treatment duration	Same
Electrical power	100-240Vac	Not public available.	110-120V	Similar Note 3
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 6060-2-57	60601-1: 2012 60201-1-2: 2014	Same

Comparison in Detail(s):

Note 1:
The “intensity” and “treatment dose” are very close to the predicate devices. Their wavelength is the same, the “intensity” and “treatment dose” are very closed to the primary predicate device. So, these differences will not affect the safety and effectiveness of the subject device compared to the predicate device.

Note 2:
The recommended treatment time for the subject device is 10-30 minutes each day, the 10 minutes limit is the same as K230336, and the 30 minutes limit is the same as the K211038. Moreover, the “intensity” and “treatment dose” are close to the two predicate devices. So, the slightly difference will not raise any safety or effectiveness issues.

Note 3:
The electrical power of subject device is different from predicate device, but it meets the requirement of IEC 60601-1. So, the difference will not raise any safety or effectiveness issues.

Final Conclusion:
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K211038 and K230336.

8. Date of the summary prepared: May 13, 2025