June 26, 2026

Ziree Co., Ltd.
% Linda Li
Compliance Officer
Huaxiajiamei (Beijing) Information Consulting Co.,Ltd
B2 Floor, Zhongguancun Dongsheng Science And Technology Park
66 Xixiaolu Rd., Haidian District
Beijing, 100192
China

Re: K261253
Trade/Device Name: Laser Hair Growth Devices (HR-H1, HR-H2, HR-H3, HR-H4, HR-H5, HR-H6, HR-H7, HR-H8, HR-H9, HR-H10, HR-I1, HR-I2, HR-I3, HR-I4, HR-I5)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 16, 2026
Received: April 16, 2026

Dear Linda Li:

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: 2026.06.26 00:46:23 -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)*
K261253

Device Name
Laser Hair Growth Devices (HR-H1, HR-H2, HR-H3, HR-H4, HR-H5, HR-H6, HR-H7, HR-H8, HR-H9, HR-H10, HR-I1, HR-I2, HR-I3, HR-I4, HR-I5)

Indications for Use *(Describe)*
Laser Hair Growth Devices is used to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classification of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to 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

K261253

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: June 18, 2026

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Ziree Co., Ltd.
Address:	Room 606, Floor 6th, Unit 1, Building 6, Chaoshi Intelligent Industrial Park, No.37 Xinyuan Road, Tianxin District, Changsha City, 410114 Hunan Province ， CHINA
Contact person:	Aijie Peng
Title:	Manager
E-mail:	3527148947@qq.com
Tel:	86-13312989605

2. Device Identification

510(K) number:	K261253
Trade/Device Name:	Laser Hair Growth Devices (HR-H1、HR-H2、HR-H3、HR-H4、HR-H5、HR-H6、HR-H7、HR-H8、HR-H9、HR-H10、HR-I1、HR-I2、HR-I3、HR-I4、HR-I5)
Models:	HR-H1、HR-H2、HR-H3、HR-H4、HR-H5、HR-H6、HR-H7、HR-H8、HR-H9、HR-H10、HR-I1、HR-I2、HR-I3、HR-I4、HR-I5
Common name:	LASER, COMB, HAIR
Regulation Number:	890.5500
Regulation Description:	Infrared lamp
Regulation Class:	Class 2
Panel:	General & Plastic Surgery
Product Code:	OAP

3. Predicate Device

510(K) number:	K192627
Trade/Device Name:	Laser Hair Growth Cap
Models:	TW280, TW272, TW147, TW080
Common name:	LASER, COMB, HAIR
Regulation Number:	890.5500
Regulation Description:	Infrared lamp
Regulation Class:	Class 2

Panel:	General & Plastic Surgery
Product Code:	OAP

4. Indication for Use

The Laser Hair Growth Devices (HR-H1, HR-H2, HR-H3, HR-H4, HR-H5, HR-H6, HR-H7, HR-H8, HR-H9, HR-H10, HR-I1, HR-I2, HR-I3, HR-I4, HR-I5) is used to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classification of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to IV.

5. Device Description

The Laser Hair Growth Devices consists of Laser hair growth Cap、USB Power Cable、Manual and Warranty Card/Certificate of Conformity.

Laser diodes are the core components of Laser Hair Growth Devices, typically emitting low-energy lasers (LLLT) at a red wavelength of 650 ± 10 nm. The light source of the laser hair Growth Devices is visible red light, it is used for promoting hair growth.

6. Compared to Predicate Device

Compared to the predicate devices, the subject device has the same intended use, similar product design, similar performance, same safety as the predicate device, the summarized comparison information is listed in the following table ：

SE Comparison Elements	Subject Device (Laser Hair Growth Devices)	Predicate Device(Laser Hair Growth Cap) K192627	Comparison Elements
Trade name	Laser Hair Growth Devices	Laser Hair Growth Cap	N/A
Classification name	Infrared Lamp	Infrared Lamp	
Product code	OAP	OAP	

Intended use/Indications forUse	Laser Hair Growth Devices is used to promote hair growth in males with androgenic alopecia who have Norwood-hamilton classification of IIa~V or females with androgenic alopecia who have Ludwig-Savin Classifications of I~II and both with Fitzpatrick Skin Phototypes I to IV	Laser Hair Growth Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classification of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fritzpatrick Skin Protytpe I-IV.	Same
Location for use	OTC application	OTC application	Same
Type of Light	Low level laser therapy (LLLT); Laser diodes	Low level laser therapy (LLLT); Laser diodes	Same
Wavelength	650nm±10nm	650nm	Same
Amount of diodes laser	HR-H1：98 HR-H2: 132 HR-H3：172 HR-H4：212 HR-H5：272 HR-H6：98 HR-H7：132 HR-H8: 172 HR-H9：212 HR-H10:n272 HR-I1: 98 HR-I2：132 HR-I3: 172 HR-I4: 212 HR-I5: 272	TW280:280 TW272: 272 TW147: 147 TW080:80	Note1
Energy of per laser diode	5mW	5mW	Same
Classification according to IEC60825-1	Class 3R	Class 3R	Same
Treatment time	Each treatment :30 min； 2-3 treatments per weeks; about10-12 weeks.	Each treatment: 30min; 16 weeks, 3 times per week spaced out every other day	Note 2

Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Male: Norwood-Hamilton IIa~V Female: Ludwig-Savin I~II	Same
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Same
Helmet/Cap design	Helmet/Cap	Cap	Note 3
Dimension (L*W*H)	Cap/small size： 18.9*21.7*9.6cm Cap/large size： 19.2*22*11.4mm Helmet：22*26*13.6mm	22*18*9cm	
Weight	HR-H1：0.2Kg HR-H2:0.21Kg HR-H3：0.22Kg HR-H4：0.23Kg HR-H5：0.24Kg HR-H6：0.23Kg HR-H7：0.24Kg HR-H8:0.25Kg HR-H9：0.26Kg HR-H10:0.27Kg HR-I1:0.65Kg HR-I2：0.66Kg HR-I3:0.67Kg HR-I4:0.68Kg HR-I5:0.69Kg	TW280:0.32Kg TW272:0.30Kg TW147: 0.26Kg TW080:0.25Kg	Note 4
Environment for operation	Ambient temperature: 5°C ~ 40 °C (41°F~104°F) Relative humidity: not greater than 80%RH	Temperature:5℃~30℃ (41℉~8℉) Humidity: 15%~90%	Note 5
Environment for storage	Temperature： -20℃~50℃ (-4 ~122) relative humidity：not exceeding 93%	Temperature: -40℃ ~70℃ (-40℉~158℉) Humidity: 10%~100%	

Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2, IEC 60601-1-6 and IEC60825-1	Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60825-1 Complied with IEC 62133 (Battery pack) Complied with IEC 60950-1 (Adapter)	Note 6
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5,ISO 10993-10 and ISO 10993-23.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Note 7
Power Density (mW/cm2)	HR-H11.06 HR-H2: 1.42 HR-H3：1.85 HR-H4：2.28 HR-H5：2.93 HR-H6：0.88 HR-H7：1.18 HR-H8: 1.54 HR-H9：1.89 HR-H10: 2.43 HR-I1: 0.99 HR-I2:1.34 HR-I3: 1.74 HR-I4: 2.15 HR-I5:2.76	Not Publicly Available	Note 8

Note 1:

The subject device utilizes a different number of laser diodes compared to the predicate device. However, both devices use the same wavelength, operating mode (continuous low-level laser therapy), and same energy of per laser diode.

Performance testing demonstrates that the variation in the number of diodes does not alter the device's mechanism of action, energy delivery per treatment area, or safety profile.

Therefore, this difference represents an engineering design variation rather than a new technological characteristic. It does not raise new questions of safety or effectiveness, supporting a conclusion of substantial equivalence between the subject and predicate devices.

Note 2:

The subjects and predicate devices have the same intended use: to promote hair growth through low-intensity laser therapy (LLLT).

The test equipment was programmed with different recommended treatment cycles and

frequencies (each treatment: 30 minutes; 16 weeks, 3 times per week spaced out of every other day) compared to the equivalent device.
This difference represents a change in user instructions, rather than a change in device technology.
The energy delivered in each treatment course is maintained within the same clinically established safe and effective range as the equivalent device.
Performance tests have confirmed that differences in treatment regimens do not lead to new safety or efficacy issues. Therefore, the main device is considered to be essentially equivalent to the equivalent device.

Note 3:

The differences in appearance and structure do not introduce new safety or effectiveness issues, and the expected use is consistent; The difference between Helmet and Cap belongs to the design/configuration difference in appearance and wearing structure, rather than the difference in technical principles or energy transfer methods;
The wavelength and energy of per laser diode are consistent, and structural differences do not pose any new risks.

Note 4:

The technical features remain unchanged, and the laser wavelength, power output, electrical parameters, and thermal performance are consistent. The weight difference comes from the shell material, structural design, or heat dissipation method, which does not affect the laser performance or user safety.
It can be proven through performance testing, electrical safety testing (IEC 60601 series), ISO 10993-23, and risk analysis that existing differences in weight has not caused new safety issues.

Note 5:

The above items, “Environment for Operation” and “Environment for Storage” of subject device are slightly different from the predicate devices, but it will not affect the main function and the intended use of the device as they all also comply with IEC 60601-1 requirements. **Note 6：**
The tested equipment does not have a power adapter as a factory component, but users are required to use a medical grade adapter that complies with IEC 60601-1 (as reflected in the instruction manual). This is a system configuration variation that does not change the electrical principles or affect safety. As long as the manufacturer's instructions and control measures are sufficient, it is considered an acceptable variation.

Note 7:

The subject device underwent stimulus assessment based on the latest ISO 10993-23 standard, which provides a more scientific and ethical evaluation method. Compared to traditional animal testing based on ISO 10993-10 for predicate devices, the testing coverage of Subject devices is wider and meets current regulatory requirements, further verifying the safety equivalence or superiority of the device in terms of biocompatibility. **Note 8：**
Although quantitative irradiance and energy density data are not available for the predicate device (K192627), a comparative engineering assessment was performed based on device

design specifications, including wavelength (650 nm), number of laser diodes, and optical output power per diode (5 mW).
The calculated irradiance and energy density of the subject device fall within expected ranges for LLLT-based devices and are consistent with the intended therapeutic mechanism.
Differences in the number of laser diodes result in variations in treatment coverage area rather than changes to the fundamental technological characteristics or mode of action of the device.

7.Non-Clinical Performance Testing

The following non-clinical performance testing was conducted to support the substantial equivalence determination for the subject device.

1) Biocompatibility Testing

The biocompatibility evaluation of the body-contacting materials of the Laser Hair Growth Device was conducted in accordance with ISO 10993-1. Testing included:

- ISO 10993-5:2009 Tests for In Vitro Cytotoxicity
- ISO 10993-10:2021 Tests for Skin Sensitization
- ISO 10993-23:2021 Tests for Skin irritation

The results demonstrated that the device is biocompatible for its intended use.

2) Electrical and EMC Safety

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020+ES Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015+A1:2020 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 60601-1-2:2014+A1:2020 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard:electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6:2010+A1:2013+A2:2020 Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
- IEC TR 60601-4-2: 2016Medical electrical equipment. Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements certifies the laser system to classification 3R, which is the same as the predicate devices.

3）Software Verification and Validation Testing

Software verification and validation testing were conducted and basic level of documentation

was provided as recommended by FDA'S Guidance for Industry and FDA

Staff, "Content of Premarket Submissions for Device Software Functions (2023)."

4) Performance Testing

A dedicated performance testing program was conducted to evaluate the functional performance of the device under normal operating conditions.

The performance testing included the following evaluations:

* Optical output power verification per laser diode
* Laser wavelength accuracy verification
* Irradiance (power density) measurement across the treatment area
* Spatial uniformity of optical output
* Output stability under continuous operation
* Operating time / treatment cycle verification
* Surface temperature evaluation during operation
* Acoustic noise measurement during normal use conditions

All performance testing was conducted using calibrated test equipment as described in the System Test Report and associated validation documentation.

The results of these evaluations confirm that the device operates within its specified performance specifications and consistently delivers the intended low-level laser therapy (LLLT) optical output under normal operating conditions for its intended use.

8. Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

9. Conclusion

The subject device and predicate device have similar technical features in terms of basic design, characteristics, operating methods, working modes, applications, and expected uses. The subject device will not pose any new potential safety risks and its performance is substantially equivalent to the predicate device.