



June 16, 2026

Zdeer Technology (Henan) Co., Ltd.  
Wenlin Xiang  
Manager  
East Of Wei Wu Rd. And S. Of Qin Gong E. Rd.,  
Toubao Village Committee, Laotown Town  
Changge, Xuchang City, Henan 461500  
China

Re: K260899

Trade/Device Name: Laser Hair Growth Device (F21151, F21152, F21153, F21154, F21155, F21156,  
F21157, F21158, F21159)

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: OAP

Dated: March 18, 2026

Received: March 18, 2026

Dear Wenlin Xiang:

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](mailto: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: 2026.06.16  
19:12:44 -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

510(k) Number (if known)

K260899

Device Name

Laser Hair Growth Device (F21151, F21152, F21153, F21154, F21155, F21156, F21157, F21158, F21159)

Indications for Use (Describe)

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.

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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# K260899 - 510(k) Summary

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

**Date: 2026-05-21**

## I. Submitter

|                        |  |
|------------------------|--|
| <b>Manufacturer:</b>   | Zdeer Technology (Henan) Co., Ltd<br>East of Wei Wu Road and south of Qin Gong East Road,<br>Toubao Village Committee, Laotown Town, Changge, Xuchang<br>City, Henan Province, P.R. China<br>+86-15637477318 |
| <b>Direct contact:</b> | Wenlin Xiang (Manager)<br>Tel: +86-15527272371<br>Email: 1132075798@qq.com   |

## II. Correspondent Consultant

Zdeer Technology (Henan) Co., Ltd

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Changge, Xuchang City, Henan Province, P.R. China

Wenlin Xiang (Manager)

Tel: +86-15527272371

Email: 1132075798@qq.com

## III. Device

|                                |   |
|--------------------------------|---|
| <b>Trade/Proprietary Name:</b> | Laser hair growth device  |
| <b>Model:</b>                  | F21151, F21152, F21153, F21154, F21155, F21156,<br>F21157, F21158, F21159 |
| <b>Common Name:</b>            | Laser hair growth device  |
| <b>Classification Name:</b>    | Laser, Comb, Hair   |
| <b>Classification:</b>         | Regulation Number: 21 CFR 890.5500  |
| <b>Product Code1:</b>          | OAP   |

|                         |                   |
|-------------------------|-------------------|
| <b>Review Panel:</b>    | Physical Medicine |
| <b>Regulatory Class</b> | II                |

#### IV. Predicate Device

| <b>Applicant</b>                            | <b>Predicate Device</b> | <b>510(k) Number</b> |
|---|-------------------------|----------------------|
| Freedom Laser Therapy, Inc.                 | ID-510 iRestore Elite   | K222081              |
| Shenzhen CosBeauty Technology Co., Ltd.     | Hair Care 88            | K213447              |
| Shenzhen Kaiyan Medical Equipment Co., Ltd. | M-130,M-300;M-180A      | K253669              |

#### V. Device Description

The device is a low-level laser system operating at  $650 \pm 20\text{nm}$ . The physical configuration is that of a helmet containing an inner and outer liner, stabilized with a silicone pad and a pair of headbands. The device helmet is constructed from ABS plastic. An internal lithium battery should be charged by a 5V, 2A adapter which complies with safety standards (not provided by zdeer). The helmet contains 88, 120, 160, 200, 240, 280, 320, 360 and 400 units of 5 mW diode lasers that emit red light. This system delivers fixed laser emission levels measured to be a total of 440, 600, 800, 1000, 1200, 1400, 1600, 1800, 2000 mW, which cannot be altered by the operator. The treatment durations are also fixed by design: 30 minutes for models F21151~5 and 20 minutes for models F21156~9 respectively

Laser hair growth device is a dome-shaped low-level laser therapy (LLLT) device designed to promote hair growth in women and men by exposing the entire scalp to the light therapy of visible red light-emitting diodes at 650nm and 5 mW each. Laser hair growth device includes 9 models, F21151, F21152, F21153, F21154, F21155, F21156, F21157, F21158, F21159. F21159 is the typical model which has maximum output. All models are the same in structure, intended use, performance and operation. The difference is the number of diodes and laser emission type.

#### VI. Indications for Use

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.

**VII. Comparison of Technological Characteristics With the Predicate Device**

Laser hair growth device raises no safety or efficacy concerns when compared to the predicate devices.

A technical comparison to the predicate is provided below:

| <b>Comparison Elements</b>           | <b>Subject Device</b>   | <b>Predicate Device I</b>  | <b>Predicate Device II</b>  | <b>Predicate Device III</b>  | <b>Comparison</b> |
|--------------------------------------|---|--|---|--|-------------------|
| K Number                             | Pending   | K222081  | K213447   | K253669  | /                 |
| Trade name                           | Laser hair growth device  | ID-510 iRestore Elite  | LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210   | Aduro Hair Growth; Truderm Halo Hair growth system   | /                 |
| Model                                | F21151, F21152, F21153, F21154, F21155, F21156, F21157, F21158, F21159  | ID-510 iRestore Elite  | Hair Care 88  | M-130,M-300;M-180A   | /                 |
| Classification name                  | Laser, Comb, Hair   | Laser, Comb, Hair  | Laser, Comb, Hair   | Laser, Comb, Hair  | /                 |
| Product code                         | OAP   | OAP  | OAP   | OAP  | /                 |
| Intended purpose/Indications for Use | Laser hair growth device is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and | The ID-510 iRestore Elite is indicated to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V, and in females with androgenic alopecia | LLLT Laser Hair Growth Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with | 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 | Same              |

|                                  |  |  |   |   |  |
|----------------------------------|--|--|---|---|--|
|                                  | both with Skin Phototypes I-IV.  | who have Ludwig-Savin Classifications of I-II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV. | androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV. | 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. |  |
| Location for use                 | Head   | Head   | Head  | Head scalp  | Same   |
| OTC or Rx <sub>only</sub>        | OTC  | OTC  | OTC   | OTC   | Same   |
| Type of laser                    | Laser diodes   | Laser diodes   | Laser diodes  | Laser diodes  | Same   |
| Wavelength of laser and LLLT     | 650 ± 20nm   | 680 ± 10nm<br>625 ± 10 nm and 655 ± 10nm   | 650 nm ± 10 nm  | Red+laser 650 nm +/-5nm<br>Red 660nm +/-10nm  | Same red laser   |
| Amount of laser diodes           | 88,120 160, 200, 240,280, 320, 360, 400  | 300 units of 5 mw diode lasers and 200 units of 5 mw LED   | 88  | M-130: 130 Red LEDs<br>M-180A: 180 Red LEDs<br>M-300: 200 Red LEDs +100 Laser   | Energy emitted is within the range of the Predicate Device |
| Irradiance (mW/cm <sup>2</sup> ) | <5mW/cm <sup>2</sup>   | /  | /   | <5 mW/cm <sup>2</sup>   | Minor different Note1                                      |
| Total dose(J/cm <sup>2</sup> )   | F21151~5: 7.80J/cm <sup>2</sup> ,<br>7.81J/cm <sup>2</sup> , 7.68J/cm <sup>2</sup> ,<br>7.75J/cm <sup>2</sup> , 7.66J/cm <sup>2</sup> ,<br>F21156~9: 3.09J/cm <sup>2</sup> , | /  | /   | M-130,M-180A:3J/cm <sup>2</sup><br>M-300: 7.5J/cm <sup>2</sup>  | Minor different Note 1                                     |

|   |  |  |  |   |  |
|---|--|--|--|---|--|
|   | 3.18J/cm <sup>2</sup> , 3.23J/cm <sup>2</sup><br>3.12J/cm <sup>2</sup> , |  |  |   |  |
| Energy of per laser diode               | ≤5mW   | 5mW  | 5mW ± 20%  | 5mW   | Same   |
| Classification according to IEC 60825-1 | Class 3R   | Class 3R   | Class 3R   | Class 3R  | Same   |
| Treatment time                          | 16 weeks, for 30/12-minute treatment times                               | 16 weeks, for 12-minute treatment times                                  | 16 weeks, for 30-minute treatment times                                  | for 16 weeks<br>M-130,M-180A:10 minutes<br>M-300: 25 minutes  | Does not raise any new questions of safety or effectiveness as compared to the predicate device. |
| Treatment frequency                     | 3 times per week spaced out every other day                              | 3 times per week spaced out every other day                              | 3 times per week spaced out every other day                              | every other day   | Same   |
| Applicable people                       | Norwood-Hamilton IIa~V (males)<br>Ludwig-Savin I~II (females)            | Norwood-Hamilton IIa~V (males)<br>Ludwig-Savin I~II (females)            | Norwood-Hamilton IIa~V (males)<br>Ludwig-Savin I~II (females)            | Norwood-Hamilton IIa~V (males)<br>Ludwig-Savin I~II (females) | Same   |
| Applicable skin                         | Fitzpatrick Skin Phototypes I-IV   | Fitzpatrick Skin Phototypes I-IV   | Fitzpatrick Skin Phototypes I-IV   | Fitzpatrick Skin Phototypes I-IV                              | Same   |
| Shape design                            | Helmet   | Helmet   | Helmet   | Helmet  | Same   |
| Safety feature                          | Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 60825-1 | Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 60825-1 | Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 60825-1 | Complied with IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2      | Same   |

|                  |  |  |   |   |      |
|------------------|--|--|---|---|------|
| Biocompatibility | All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23. | All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23. | All body-contacting materials are complied with ISO 10993-5 and ISO 10993-10, ISO 10993-23. | All body-contacting materials are complied with ISO 10993-5 and ISO 10993-10, ISO 10993-23. | Same |
|------------------|--|--|---|---|------|

Note1: Although the irradiance and total dose values were not obtained from Predicate Devices I and II, they fall within the established range of Predicate Device III for models F21156~9. For models F21151~5, the irradiance and total dose are slightly higher than those of Predicate Device III; however, these minor variances between the subject device and the predicate devices do not raise new questions of safety or effectiveness.

## VIII. Performance Data

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

### 1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of Laser hair growth device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recommended by FDA. The testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, 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 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

### 2) Electrical and EMC Safety

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

- IEC 60601-1:2020 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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 60601-1-2 :2020 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests

In addition, testing to IEC 60825-1:2007 certifies the laser system to classification 3R, which is the same as the predicate devices.

### 3) Software verification and validation

Software documentation consistent with Basic Documentation was provided. Verification and validation test were conducted according to the FDA “Guidance for Pre-Market Submissions and for Software Contained in Medical Devices”

### Summary

Based on the above performance as documented in this application, the Laser hair growth device was found to have a safety and effectiveness profile that is the same as the predicate device.

## VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the laser hair growth device is to be concluded substantially equivalent with its predicate devices.