June 16, 2026

Hubei YJT Technology Co., Ltd
% Gamma Zhang
RA Manager
Tacro
Building 12, Jindi Xiandao Blue Valley, No.2 Qiannong 1st Rd
Xiaoshan Dist.
Hangzhou, Zhejiang
China

Re: K253231
Trade/Device Name: Laser Hair Growth System (Laser Cap 128, Laser Helmet 272, Laser Helmet 352, Laser Helmet 552, Laser Helmet 500)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 28, 2025
Received: September 29, 2025

Dear Gamma Zhang:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.06.16 20:46:37 -04'00'

Tanisha Hithe
Assistant Director
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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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K253231

Device Name
Laser Hair Growth System (Laser Cap 128, Laser Helmet 272, Laser Helmet 352, Laser Helmet 500, Laser Helmet 552)

Indications for Use *(Describe)*
Laser Hair Growth System is indicated to promote hair growth in males with androgenicalopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenicalopecia who have Ludwig-Savin Classifications of I-II and both with Skin Phototypes 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 #K253231

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

**Date: 2026-06-10**

## I. Submitter

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## III. Device

Type of 510(k): Traditional
Common Name: Laser Hair Growth System
Trade Name: Laser Hair Growth System
Model: Laser Cap 128, Laser Helmet 272, Laser Helmet 352, Laser Helmet 500, Laser Helmet 552
Classification Name: Laser, Comb, Hair
Regulation Number: 21 CFR 890.5500
Review Panel: Physical Medicine
Regulatory Class: II
Product Code: OAP

## IV. Predicate Device

| Applicant | Predicate Device | 510(k) Number |
|---|---|---|
| Freedom Laser Therapy Inc. | ID-510 iRestore Elite | K222081 |
| Capillus LLC | Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352 | K163170 |

## V. Device Description

Laser Hair Growth System 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. The Laser Helmet or Laser Cap is designed with an inner flexibility plastic cap and outer cloth cap (containing the electronics and laser array).

## VI. Indications for Use

Laser Hair Growth System 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 both with Skin Phototypes I-IV.

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

Laser Hair Growth System raises no safety or efficacy concerns when compared to the predicate devices.

A technical comparison to the predicate is provided below:

| Comparison Elements | Subject Device | Predicate Device I | Comparison |
|---|---|---|---|
| K Number | K253231 | K163170 | / |
| Trade name | Laser Hair Growth System | Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352 | / |
| Model | Laser Cap 128, Laser Helmet 272, Laser Helmet 352 | / | / |
| Classification name | Laser, Comb, Hair | Laser, Comb, Hair | / |
| Product code | OAP | OAP | / |
| Intended use/Indications for Use | Laser Hair Growth System 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 both with Skin Phototypes I-IV. | The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood -Hamilton Classifications of IIa to 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; both with Fitzpatrick Skin Types I to IV. | Same |
| Location for use | Head | Head | Same |
| Type of lights | Low Level Laser Therapy (LLLT) | Low Level Laser Therapy (LLLT) | Same |
| Wavelength | 650nm | 650nm | Same |
| Amount of laser diodes | Laser Cap 128: 128<br>Laser Helmet 272: 272<br>Laser Helmet 352: 352 | 82, 202, 272, 302, 312, 352 | Same |
| Energy of per laser diode | <5mW | <5mW | Same |
| Energy density | Laser Cap 128: 1.63 $mW/cm^2$<br>Laser Helmet 272: 2.12 $mW/cm^2$<br>Laser Helmet 352: 2.74 $mW/cm^2$ | Capillus 272: 2.7454 $mW/cm^2$<br>Capillus 202: 2.2469 $mW/cm^2$<br>Capillus 82: 2.1088 $mW/cm^2$ | |
| Classification according to IEC 60825-1 | Class 3R | Class 3R | Same |

| Comparison Elements | Subject Device | Predicate Device I | Comparison |
|---|---|---|---|
| Maximum Treatment time | 30 minutes | 30 minutes | Same |
| Treatment frequency | 3 times per week spaced out every other day | 3 times per week spaced out 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) | Same |
| Applicable skin | Fitzpatrick Skin Phototypes I-IV | Fitzpatrick Skin Phototypes I-IV | Same |
| Shape design | Helmet | Helmet | Same |
| Safety feature | Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 | Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 | Same |

| Comparison Elements | Subject Device | Predicate Device I | Predicate Device II | Comparison |
|---|---|---|---|---|
| K Number | K253231 | K222081 | K163170 | / |
| Trade name | Laser Hair Growth System | ID-510 iRestore Elite | Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352 | / |
| Model | Laser Helmet 552, Laser Helmet 500 | / | / | / |
| Classification name | Laser, Comb, Hair | Laser, Comb, Hair | Laser, Comb, Hair | / |
| Product code | OAP | OAP | OAP | / |

| Comparison Elements | Subject Device | Predicate Device I | Predicate Device II | Comparison |
|---|---|---|---|---|
| Intended use/Indications for Use | Laser Hair Growth System 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 both with Skin Phototypes I-IV. | 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 androgenetic alopecia who have Ludwig-Savin Classifications of I<br>II, and in both, Fitzpatrick Classification of Skin Phototypes I to IV. | The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood -Hamilton Classifications of IIa to 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; both with | Same |
| Location for use | Head | Head | Head | Same |
| Type of lights | Low Level Laser Therapy (LLLT) | Low Level Laser Therapy (LLLT) | Low Level Laser Therapy (LLLT) | Same |
| Laser Wavelength | 655nm | 625±10nm and 655nm±10nm | 650nm | Same |
| LED Wavelength | 655nm | 680nm±10mm | No LED | Same |
| Amount of laser diodes | Laser Helmet 500: 300<br>Laser Helmet 552: 352 | 300 | 82, 202, 272, 302, 312, 352 | Same |
| Amount of LED | Laser Helmet 500: 200<br>Laser Helmet 552: 200 | 200 | No LED | Same |
| Energy of per laser diode | <5mW | <5mW | <5mW | Same |
| Energy density | Laser Helmet 500: 2.33 $mW/cm^2$<br>Laser Helmet 552: 2.74 $mW/cm^2$ | Not known | Capillus 272: 2.7454 $mW/cm^2$<br>Capillus 202: 2.2469 $mW/cm^2$<br>Capillus 82: 2.1088 $mW/cm^2$ | Same |
| Classification according to IEC 60825-1 | Class 3R | Class 3R | Class 3R | Same |

| Comparison Elements | Subject Device | Predicate Device I | Predicate Device II | Comparison |
|---|---|---|---|---|
| Treatment time | 12 minutes | 12 minutes | Indefinite | Same |
| Treatment frequency | 3 times per week spaced out every other day | Daily | 16 weeks, spaced out every other day | Same |
| Applicable people | Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females) | Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II | Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II | Same |
| Applicable skin | Fitzpatrick Skin Phototypes I-IV | Fitzpatrick Skin Phototypes I-IV | Fitzpatrick Skin Phototypes I-IV | Same |
| Shape design | Helmet | Helmet | Helmet | Same |
| Safety feature | Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 | Complied with IEC60601-1, IEC60601-1-11, IEC60601-1- | Complied with IEC60601-1, IEC60601-1-11, | Same |

**Conclusion:**

Laser Hair Growth System(Model: Laser Cap 128, Laser Helmet 352, Laser Helmet 272) is substantially equivalent to predicate devices Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352, and Laser Hair Growth System(Model: Laser Helmet 500, Laser Helmet 552) is substantially equivalent to predicate devices ID-510 iRestore Elite, and Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352.

## VIII. Performance Data

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

**1) Biocompatibility**

The patient-contacting materials of the subject device are evaluated in accordance with Attachment G of the FDA Guidance document titled "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued September 2023). Because all materials contacting intact skin are covered under Attachment G, traditional biocompatibility testing data is not required. The biocompatibility of the subject device is adequately addressed through compliance with Attachment G.

**2) Electrical and EMC Safety**

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

- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 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 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems
- IEC 60601-2-57 Edition 1.0 2011-01 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 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests
- IEC /TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

In addition, testing to IEC 60825-1 Edition 2.0 2007-03 certifies the laser system to classification 3R, which is the same as the predicate devices.

**Summary**

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

## IX. 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, Laser Hair Growth System is to be concluded substantially equivalent to its predicate devices.