July 17, 2026

Shenzhen Chuanghong Zhilian Technology Co., Ltd.
% Bing Huang
Registration specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K261675
Trade/Device Name: CHZL Red Light Therapy Hair Growth Cap (Model(s):CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: May 21, 2026
Received: May 21, 2026

Dear Bing Huang:

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: 2026.07.17 16:56:48 -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.	K261675

Please provide the device trade name(s).

CHZL Red Light Therapy Hair Growth Cap (Model(s):CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D)

Please provide your Indications for Use below.

CHZL Red Light Therapy Hair Growth Cap (Model(s): CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D) is indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenic 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.
The device is intended for use in adults (22 years of age and older).

Please select the types of uses (select one or both, as applicable).	☐ 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

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

K261675

Date: 2026-07-09

I. Submitter's Information

Sponsor Name: Shenzhen Chuanghong Zhilian Technology Co., Ltd
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Distributor

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Post code: 518000
Tel.: +86 0755-27781086
Contact person: Ya Huang
Email: chzl989@163.com

Manufacture

Manufacture Name:GYMMAX TECHNOLOGY SHENZHEN CO.,LTD.
Address: 4F & 5F, 4th Bldg, Heping Complex (4th Bldg. Huimingsheng Technology Park) Fuhai Subdistrict, Baoan District Shenzhen City, Guangdong, CN
Post code: 518103
Tel.:+86 0755-29124050

II. Device

Name of Device: CHZL Red Light Therapy Hair Growth Cap
Model(s): CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D
Common or Usual Name: Laser, Comb, Hair
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II

Product Code: OAP
Regulation Number: 21CRF 890.5500
Review Panel: General & Plastic Surgery

III. Predicate Device

Manufacturer	Predicate Device	510(k) Number	Clearance Date
Beijing Top Laser Technology Co., Ltd.	Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap	K240456	May 22,2024
SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD	HIGHERDOSE Red Light Hat (HG-120K)	K242363	November 20,2024
Dongguan Boyuan Intelligent Technology Co., Ltd.	Hair Growth Device (KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S)	K250308	April 29, 2025

IV. Device Description

CHZL Red Light Therapy Hair Growth Cap (Model(s): CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D) is 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 laser diodes (LDs) and LEDs at 650nm and 5mW each, The LDs and LEDs are contained inside a lightweight cap. The device is powered by a built-in rechargeable lithium battery and automatically turns of after 10 or 20 minutes. The device has a controller for operating the on /off , mode switch and time switch.

V. Indications for Use

CHZL Red Light Therapy Hair Growth Cap (Model(s): CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D) is indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenic 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.

The device is intended for use in adults (22 years of age and older).

VI. Comparison of Technological Characteristics With the Predicate Device

CHZL Red Light Therapy Hair Growth Cap is compared with the following Predicate Devices in terms of intended use, design, specifications, and performance:

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 2	Predicate Device 3	Remark
510(k) Number	K261675	K240456	K242363	K250308	/
Trade name	CHZL Red Light Therapy Hair Growth Cap (Models: CHZL-120BK-L52D,CHZL-120BK-L53D,CHZL-120BK-L54D)	Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap	HIGHERDOSE Red Light Hat (HG-120K)	Hair Growth Device (KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S)	/
Manufacturer	GYMMAX TECHNOLOGY SHENZHEN CO.,LTD.	Beijing Top Laser Technology Co., Ltd.	SHENZHEN KAIYAN MEDICAL EQUIPMENT CO., LTD	Dongguan Boyuan Intelligent Technology Co., Ltd.	/
Regulation number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Product code	OAP	OAP	OAP	OAP	Same
Device classification	Class II	Class II	Class II	Class II	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Indication for use/ Intended use	CHZL Red Light Therapy Hair Growth Cap is indicated to treat Androgenic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who	The HIGHERDOSE Red Light Hat is a home wearable light-emitting diode phototherapy device with proven wavelengths of light 650nm±10nm Red light, which are used	Hair Growth Device is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, in males with and rogenetic alopecia who	Same

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 2	Predicate Device 3	Remark
	Androgenic 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. The device is intended for use in adults (22 years of age and older).	have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of Ila - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have LudwigSavin Scale 1-1 to 1-4, 11-1, 11-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	
Intended User	Female and Males	Female and Males	Female and Males	Female and Males	Same
Intended location of use	Scalp	Scalp	Scalp	Scalp	Same
Helmet/Cap design	Cap	Cap	Cap	Helmet	Same
Mode of Operation	Low-level laser diodes and light-emitting diodes	Low-level laser diodes and light-emitting diodes	Light emitting diodes	Visible red laser	Same
Wavelength	650nm±10nm	650 nm	Red: 650nm±10nm	650±20nm	Same
Amount of diodes	CHZL-120BK-L52D: 120LEDs CHZL-120BK-L53D: 120LDs CHZL-120BK-L54D: 60LEDs+60LDs	128 model: 57LDs+77LEDs 162 model: 65LDs+97LEDs 288 mode:115LDs+173LEDs	120 Red LEDs	56, 88, 120,200	Same

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device 2	Predicate Device 3	Remark
Power Output	⩽5mW	5mW per light	Unknown	5mW	Same
Classification according to IEC 60825-1	Class 3R	Class 3R	/	Class 3R	Same
Treatment duration	10, 20minutes 10miunuet every day, for 16weeks 20minutes every other day for 16 weeks	25 minutes every day	10 minutes Every other day, for 16weeks	Each Treatment: 30 minutes. Total Treatment: once every 2 days, for 16 weeks	Same
Power supply	Rechargeable Lithium battery	Power supply	Rechargeable Lithium battery	Rechargeable Lithium battery	Same
Total Irradiance	CHZL-120BK-L52D: 1.8～4.2mW/cm^2 CHZL-120BK-L53D: 0.8～2.9mW/cm^2 CHZL-120BK-L54D: 1.3～3.4mW/cm^2	128 model: 1.43mW/cm^2 162 model: 1.68mW/cm^2 288 model: 2.47mW/cm^2	5mW/cm^2	2.56mW/cm^2	Similar **Note 1**
Distribution	Uniform	Uniform	Uniform	Unknown	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 IEC 60825-1	IEC 60601-1, IEC 60601-11, IEC 60601-2-22, IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60247	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-1-11 IEC 60601-2-57	Same
Biocompatibility feature	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10 and ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

VII.Performance Data

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

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the subject device is performed the biocompatibility evaluation 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 Sep. 4, 2020" , as recommended by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5: 2009, Biological evaluation of medical devices –Par t 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, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and EMC Safety

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

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical Electrical Equipment –Part 1: 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 60601-2-83: 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 5.0 2021-09 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 60825-1: 2014 Safety of laser products - Part 1: Equipment classification and requirements.

3) Eye Safety

- IEC 62471:2006 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***Basic Documentation*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Summary

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to 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 subject device CHZL Red Light Therapy Hair Growth Cap is to be concluded substantial equivalent to its predicate devices.