October 22, 2025

Cosmo Far East Technology Limited
℅ Kiwi Xu
Primary Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Central Ave.
Shanghai,
China

Re: K252325
Trade/Device Name: Hair Growth Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 25, 2025
Received: July 25, 2025

Dear Kiwi Xu:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.10.22 09:09:09 -04'00'

for 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.	K252325
Please provide the device trade name(s).	
Hair Growth Laser Cap	
Please provide your Indications for Use below.	
Hair Growth Laser Cap 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 Fitzpatrick Skin Phototypes I-IV.	
Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K252325

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

Date: 2025.9.5

I. Submitter

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II. Device

Type of 510(k): Traditional
Common Name: Lamp, non-heating, for promotion of hair growth
Trade Name: Hair Growth Laser Cap
Classification Name: Infrared lamp per 21 CFR 890.5500
Review Panel: General & Plastic Surgery
Regulatory Class: II
Product Code: OAP
Regulation Number: 21 CFR 890.5500

III. Predicate Device

Applicant	Predicate Device	510(k) Number
Cosmo Far East Technology Limited	Diode Laser Cap	K173678

IV. Device Description

Hair Growth Laser Cap is a dome-shaped low level laser therapy (LLLT) device is designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of laser diodes at 650nm and 5mW each. The Cap is designed with an outer plastic cover and a protective inner liner (containing the electronics and laser array) and is powered by an included battery pack.

V. Indications for Use

Hair Growth Laser Cap 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 Fitzpatrick Skin Phototypes I-IV.

VI. Comparison of Technological Characteristics With the Predicate Device

The Hair Growth Laser Cap is substantially equivalent to the predicated device based on intended use, design, specifications and performance.
The Hair Growth Laser Cap raises no safety or efficacy concerns when compared to the predicate devices.
Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

Comparison Elements	Subject Device	Predicate Device	Comparison Elements
K Number	K252325	K173678	-
Trade name	Hair Growth Laser Cap	Diode Laser Cap	-
Classification name	Infrared Lamp	Infrared Lamp	Same
Product code	OAP	OAP	Same
Intended use/Indications for Use	Hair Growth Laser Cap 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 Fitzpatrick Skin Phototypes I to IV.	Diode Laser Cap 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 Fitzpatrick Skin Phototypes I to IV.	Same
Location for use	OTC application	OTC application	Same
Type of Light	Laser diodes	Visible red light emitting diodes	Same
Wavelength	650nm	650nm	Same
Amount of diodes laser	C312: 312 C304HC: 304 C302: 302 C272:272 C244HC:244 C154HC:154 C152:152	COSMO-010: 272 COSMO-020: 148 COSMO-030: 272	-
Energy of per laser diode	5mW	5mW	Same
Classification according to IEC60825-1	Class 3R	Class 3R	Same

Comparison Elements	Subject Device	Predicate Device	Comparison Elements
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Same
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Same
Helmet/Cap design	Yes	Yes	Same
Dimension	(L*W*H) 20.3*18.1*9cm	(L*W*H) COSMO-010: 23*18*9cm COSMO-020: 22*18*9cm COSMO-030: 22*18*9cm	The product has passed the performance test and safety test. The size and weight have no impact on the product performance.
Weight	C312: 388.2g C304HC: 368.4g C302: 361.8g C272: 355.6g C244HC: 347.8g C154HC: 318.3g C152: 314.7g	COSMO-010: 0.22kg COSMO-020: 0.26kg COSMO-030: 0.26kg	
Environment for operation	Temperature:10℃~40℃ (50℉~104℉) Humidity: 20%~80%	Temperature: 10 ℃ ~30℃ (50℉~86℉) Humidity: 20%~80%	Same
Environment for storage	Temperature: -10 ℃ ~60℃ (14℉~140℉) Humidity: 20%~80%	Temperature: -10 ℃ ~60℃ (14℉~140℉) Humidity: 20%~80%	Same
Irradiance (mW/cm^2)	C312: 2.70 C304HC: 2.67 C302: 2.66 C272: 2.30 C244HC: 2.21 C154HC: 1.41 C152: 1.36	COSMO-010: 2.74 COSMO-020: 2.13 COSMO-030: 2.74	The Irradiance value of the subject device is covered by the predicated device, so the subject device is safe.
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, Complied with IEC62133 (Battery pack) Complied with IEC60950 (Adapter)	Same
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.	Same

VII. 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 the Hair Growth Laser Cap 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 June 16, 2016), as recommended by FDA.

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 TR 60601-4-2: 2016Medical electrical equipment . Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

In addition, testing to IEC 60825-1:2014 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, Hair Growth Laser Cap 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 Hair Growth Laser Cap is concluded to be substantially equivalent to its predicate device.