



October 24, 2023

Hubei YJT Technology Co.,Ltd
% Gamma Zhang
RA Manager
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Suite 405, Bldg. A Nanfeng, No.4093 Liuxian Blvd., Nanshan
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Shenzhen, Guangdong 510000
China

Re: K232356
Trade/Device Name: Laser Cap, Model: Hat-01
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 7, 2023
Received: August 7, 2023

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 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.

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,

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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)

K232356

Device Name

Laser Cap

Indications for Use (Describe)

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 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.

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510(k) Summary

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

Date: 2023-08-07

I. Submitter

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III. Device

Type of 510(k): Traditional
Common Name: Laser cap
Trade Name: Laser cap
Model: Hat-01
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
Transdermal Cap, Inc.	LaserCap Family of Lasers 300, 224, 120 & 80	K203826

Shenzhen CosBeauty Technology Co., Ltd.	LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210	K213447
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V. Device Description

Laser Cap is a hand-held cap-shaped low level laser therapy device that emits laser light designed to promote hair growth in women and men. The device provides distributed laser light to the scalp while the cap covers the user's scalp to ensure the laser light reaches the user's scalp. Model Hat-01 contains 82 laser diodes.

VI. Indications for Use

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 Skin Phototypes I-IV.

VII. Comparison of Technological Characteristics With the Predicate Device

Laser cap 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	Predicate Device II	Comparison
K Number	Pending	K203826	K213447	/
Trade name	Laser Cap	LaserCap Family of Lasers, Models 300, 224, 120 and 80	LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210	/
Model	Hat-01	80	Hair Care 88	/
Classification name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair	/
Product code	OAP	OAP	OAP	/
Intended use/Indications for Use	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 Skin Phototypes I-IV.	The LaserCap Family of Lasers, models 300, 224, 120 and 80 are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, and males who have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Skin Phototypes I to IV.	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 androgenic alopecia who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.	Same
Location for use	Head	Head	Head	Same
Type of laser	Laser diodes	Laser diodes	Laser diodes	Same
Wavelength	650nm	650nm±5nm	650nm±10nm	Same
Amount of laser diodes	82	80	88	Same
Energy of per laser diode	5mW ± 20%	5mW	5mW ± 20%	Same
Classification according to IEC 60825-1	Class 3R	Class 3R	Class 3R	Same
Treatment time	16 weeks, for 30-minute treatment times	16 weeks, for 30-minute treatment times	16 weeks, for 30-minute treatment times	Same
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	Same

510(k)s –510(k) Summary

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II	Comparison
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	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	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, IEC60601-1-2 and IEC60825-1	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1	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 ISO10993-5 and ISO 10993-10, ISO 10993-23.	Same

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 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 September 4, 2020", as recognized 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 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 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 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 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 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.

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, Laser cap is to be concluded same to its predicate devices.