January 19, 2022

Shenzhen CosBeauty Technology Co., Ltd.
℅ Tracy Che
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road,
Shenzhen, Guangdong 518052
China

Re: K213447
Trade/Device Name: LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210.
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: October 18, 2021
Received: October 25, 2021

Dear Tracy Che:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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

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)*
K213447

Device Name
LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210.

Indications for Use *(Describe)*
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.

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

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Shenzhen CosBeauty Technology Co., Ltd.
Address:	UnitA-3F, Qiao De Industrial Park, Tian Liao Guang Ming District, Shenzhen, China
Contact person:	Ares Zou
Phone number:	+86 755 8627 1293
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Email:	zougaofeng@cos-beauty.com
Date of summary prepared:	2021-10-18

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	LLLT Laser Hair Growth Cap, Model: Hair Care 88, Hair Care 135, Hair Care 210
Common name:	Lamp, non-heating, for promotion of hair growth
Regulation number:	21 CFR 890.5500
Product code:	OAP
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate and reference device

- **Predicate device**

Sponsor	Nature Incredible Inc.
Device Name and Model	CAPOGEN Laser Cap, model: CG-148, CG-272
510(k) Number	K201854
Product Code	OAP
Regulation Number	21 CFR 890.5500
Regulation Class	II

- **Reference device**

Sponsor	Transdermal Cap, Inc.
Device Name and Model	Lasercap Family of Lasers, Models 300, 224, 120 and 80

510(k) Number	K203826
Product Code	OAP
Regulation Number	21 CFR 890.5500
Regulation Class	II

(5) Description/ Design of device:

LLLT Laser Hair Growth Cap 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 photobiostimulation of visible red light-emitting diodes at 650nm and 5mW each. LLLT Laser Hair Growth Cap includes three models, Hair Care 210, Hair Care 135 and Hair Care 88. Hair Care 210 (210 diodes) is the typical model, Hair Care 135 (135 diodes) and Hair Care 88 (88 diodes) are exactly the same as the Hair Care 210 regarding structure design, intended use, performance and operation, with the difference being the diode amount. Each model has three colors, which are white, hidden color and pool blue.

(6) Indications for use:

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.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
LLLT Laser Hair Growth Cap (main unit+gasket)	PA6/PC/PVC	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Subject device	Predicate device	Reference device	Remark
Trade name	LLLT Laser Hair Growth Cap, model: Hair Care 88, Hair Care 135, Hair Care 210	CAPOGEN Laser Cap, model: CG-148, CG-272	Lasercap Family of Lasers, Models 300, 224, 120 and 80	/
510 (k) number	To be assigned	K201854	K203826	/
Manufacturer	Shenzhen CosBeauty	Nature Incredible Inc.	Transdermal Cap, Inc.	/

	Technology Co., Ltd.			
Regulation number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Regulation description	Infrared lamp	Infrared lamp	Infrared lamp	Same
Product code	OAP	OAP	OAP	Same
Class	II	II	II	Same
Indications for use/ Intended use	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.	CAPOGEN 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.	Promoting hair growth in females with Androgenetic Alopecia who have Ludwig -Savin Classifications of I-II and males who have Norwood-Hamilton Classifications of Ila - V and for both, Fitzpatrick Classifications of Skin Phototypes of I-IV.	Same
Location for use	OTC	OTC	OTC	Same
Power supply	DC5V-1A, 3500mAH lithium battery	DC5V, 2A	/	Different **Note 1**
Type of light	Visible red light-emitting diodes	Visible red light-emitting diodes	Laser diode	Same
Wavelength	650nm±10nm	650nm	650nm±5nm	Similar
Amount of laser diodes	Hair Care 88: 88 Hair Care 135:135 Hair Care 210: 210	CG-148: 148 CG-272: 272	300, 224, 120, 80	Different **Note 2**
Energy per laser diode	5mW±20%	5mW	5mW	Similar
Laser classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	Same
Treatment time	Each treatment: 30min 16 weeks, every other day (indefinite)	Each treatment: 30min 16 weeks, every other day (indefinite)	16 weeks, for 30-minute treatment times three times a week, on alternate days.	Same

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
Helmet/Cap design	Yes	Yes	Yes	Same
Dimensions	179.6*211.4*104.4mm	(L*W*H) CG-148:22*18*9cm CG-272:22*18*9cm	/	Different **Note 3**
Weight	Hair Care 88: 358g; Hair Care 135: 368g; Hair Care 210: 398g	CG-148: 0.26kg CG-272: 0.26kg	/	Different **Note 3**
Environment for operation	Temperature: 5 ℃ ～ 30℃; Humidity: ≤80%;	Temperature: 10 ℃ ~30℃ (50℉~86℉) Humidity: 20%~80%	/	Similar
Environment for storage	Temperature: 0 ℃ ～ 55℃; Humidity: ≤93%;	Temperature: -10 ℃ ~60℃ (14℉~140℉) Humidity: 20%~80%	/	Similar
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60825-1; IEC 62133 (lithium battery)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack) Complied with IEC60950 (Adapter)	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 60825-1	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Same

Comparison in details:

Note 1:

The power supply for the subject device is different from that of the predicate device, however the lithium battery of the subject device has passed IEC62133 test and the power adapter has been assessed for electrical safety test along with the main unit, so this difference should not raise any safety/effectiveness questions.

Note 2:

The number of diodes are defined by the manufacturer, although it's different from that of the predicate device, it's similar and within the range of the reference device. Since as little as 80 diodes with similar parameters of 650nm ± 5nm wavelength and 5mW energy per diode are demonstrated to be effective, 88, 135, 210 diodes should also be effective. This difference should not raise any safety/effectiveness questions.

Note 3:

Although the appearance, weight and dimensions are different between the subject and predicate device, these differences are insignificant and do not raise any safety/effectiveness problems.

Conclusion:

LLLT Laser Hair Growth Cap is substantially equivalent to the predicate device.

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the LLLT Laser Hair Growth Cap meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- ANSI AAMI ES 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- 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 60825-1, Safety of laser products - Part 1: Equipment classification, and requirements
  Testing to IEC 60825-1 certifies the laser system to classification 3R, which is the same as the predicate device.

The device has been tested for biocompatibility, it complies with the following standards.

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device LLLT Laser Hair Growth Cap is as safe, as effective, and performs as well as the legally marketed predicate device, K201854, CAPOGEN Laser Cap, model: CG-148, CG-272.