September 1, 2020

Nature Incredible Inc
% Gamma Zhang
RA Manager
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg. 1, Southward Ruifeng Business Center
Guimiao Road
Shenzhen, Guangdong 518000
China

Re: K201854
Trade/Device Name: CAPOGEN Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 6, 2020
Received: July 6, 2020

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 (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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201854

Device Name
CAPOGEN Laser Cap, Model: CG-148, CG-272

Indications for Use *(Describe)*
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-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.

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K201854

510(k) Summary

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

Date: 2020-06-28

I. Submitter

Nature Incredible Inc.
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DELAWARE 19808
Tel.: (508) 276-5155

John Lee (General Manager)
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II. Device

Type of 510(k): Traditional
Common Name: Lamp, non-heating, for promotion of hair growth
Trade Name: CAPOGEN Laser Cap, Model: CG-148, CG-272
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

The CG-272 CAPOGEN Laser 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 272visible red light-emitting 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. The CG-148 CAPOGEN Laser Cap is exactly the same as the CG-272 with the exception of the number of diodes which is respective of model (148 diodes in CG-148).

V. Indications for Use

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-IV.

VI. Comparison of Technological Characteristics With the Predicate Device

The CAPOGEN Laser Cap and predicate device Diode Laser Cap is the same product, and they only differ from trade name.
The CAPOGEN 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**
K Number	Pending	K173678
Trade name	CAPOGEN Laser Cap	Diode Laser Cap
Model	CG-148	COSMO-020
	CG-272	COSMO-030
Classification name	Infrared Lamp	Infrared Lamp
Product code	OAP	OAP
Intended use/Indications	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.	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.
Location for use	OTC application	OTC application
Type of Light	Visible red light-emitting diodes	Visible red light-emitting diodes
Wavelength	650nm	650nm
Amount of laser diodes	CG-148: 148 CG-272: 272	COSMO-020: 148 COSMO-030: 272
Energy of per laser diode	5mW	5mW
Classification according to IEC60825-1	Class 3R	Class 3R

Comparison Elements	Subject Device	Predicate Device
Treatment time	Each treatment: 30min 16 weeks, every other day (indefinite)	Each treatment: 30min 16 weeks, every other day (indefinite)
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Helmet/Cap design	Yes	Yes
Dimension	(L*W*H) CG-148:22*18*9cm CG-272:22*18*9cm	(L*W*H) COSMO-020:22*18*9cm COSMO-030: 22*18*9cm
Weight	CG-148: 0.26kg CG-272: 0.26kg	COSMO-020: 0.26kg COSMO-030: 0.26kg
Environment for operation	Temperature: 10℃~30℃ (50℉~86℉) Humidity: 20%~80%	Temperature: 10℃~30℃ (50℉~86℉) Humidity: 20%~80%
Environment for storage	Temperature: -10℃~60℃ (14℉~140℉) Humidity: 20%~80%	Temperature: -10℃~60℃ (14℉~140℉) Humidity: 20%~80%
Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack) Complied with IEC60950 (Adapter)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack) Complied with IEC60950 (Adapter)
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.

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 CAPOGEN 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 recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

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. And the charger conforms to IEC 60950 and the battery to IEC 62133.

Summary

Based on the above performance as documented in this application, CAPOGEN 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, the CAPOGEN Laser Cap is to be concluded same to its predicate devices.