June 23, 2023

Nature Incredible Inc
John Lee
General Manager
3422 Old Capitol Trail #569
Wilmington, Delaware 19808

Re: K231153
Trade/Device Name: Neuhat Hair Growth System; ibeauty.com Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 24, 2023
Received: April 24, 2023

Dear John Lee:

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231153

Device Name
Neuhat Hair Growth System
ibeauty.com Laser Cap

Indications for Use *(Describe)*
Neuhat Hair Growth System is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV.

ibeauty.com Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K231153

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

Date: 2023-06-22

1. Submitter

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DELAWARE 19808
Tel.: (508) 276-5155

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276-5155
Email: natureincredibleinc@gmail.com

2. Device

Type of 510(k): Traditional
Common Name: Lamp, non-heating, for promotion of hair growth
Trade Name: Neuhat Hair Growth System (or ibeauty.com Laser Cap)
Model: NEU180, NEU300
Regulation Name:
Review Panel: General & Plastic Surgery
Regulatory Class: II
Product Code: OAP
Regulation Number: 21 CFR 890.5500

3. Predicate Device

Applicant	Primary Predicate Device	Reference device
510(k) Number	K210169	K200464
Trade name	Hair Growth Device	LG Pra.L Derma LD Scalp Care
Model	LS-D601	/
Regulation name	Infrared Lamp	Infrared Lamp
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Regulation Class	Class II	Class II
Regulation number	21 CFR 890.5500	21 CFR 890.5500
Product code	OAP	OAP

4. Device Description

The System includes NEU180 and NEU300 two models.
NEU180 consists of 50 laser diodes with wavelength at 655nm, power ≤5mW, and 130 red light diodes with wavelength at 650 nm, power ≤5mW.
NEU300 consists of 100 laser diodes with wavelength at 655nm, power ≤5mW, and 200 red light diodes with wavelength at 650 nm, power ≤5mW.
The System is designed with an outer plastic cover and a protective inner liner (containing the electronics and laser array) and is powered by an adapter.

5. Indications for Use

Neuhat Hair Growth System is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV.

ibeauty.com Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV.

6. Comparison of Technological Characteristics With the Predicate Device

Neuhat Hair Growth System (or ibeauty.com Laser Cap) raises no safety or efficacy concerns as compared to the predicate devices.
A technical comparison to the predicate is provided below:

Comparison Elements	Subject Device	Primary Predicate Device	Reference device I	Remark
K Number	Pending	K210169	K200464	/
Trade name	Neuhat Hair Growth System (or ibeauty.com Laser Cap)	Hair Growth Device	LG Pra. L Derma LD Scalp Care	/
Model	NEU300, NEU180	LS-D601	/	/
Classification name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Same
Product code	OAP	OAP	OAP	Same

Comparison Elements	Subject Device	Primary Predicate Device	Reference device I	Remark
Intended use/Indications for Use	Neuhat Hair Growth System is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV. ibeauty.com Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with androgenic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV.	The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of1-II and Fitzpatrick Classification of Skin Phototypes I to IV.	The LG Pra.L Derma LD Scalp Care is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	Same
Intended user	Both sex	Both sex	Both sex	Same
Location for use	OTC application	OTC application	OTC application	Same
Type of Light	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Same

Comparison Elements	Subject Device	Primary Predicate Device	Reference device I	Remark
Wavelength	Laser: 655nm Red light LED: 650nm	Laser: 650-660nm Red light LED: 640-660nm	Laser: 650-667nm Red light LED: 645-665nm	Subject device is within the bandwidth of predicate and reference devices
Amount of laser diodes	NEU300 Laser diodes: 100 LED diodes: 200	Laser diodes: 26 LED diodes: 30	Laser diodes: 250 LED diodes: 250	Subject device is within the bandwidth between predicate and reference devices
	NEU180 Laser diodes: 50 LED diodes: 130			Subject device is within the bandwidth between predicate and reference devices
Energy of per laser diode	5mW	5mW	5mW	Same
Treatment time	Each treatment: 25 mins Total Treatment: 16 weeks, every other day (indefinite)	Each treatment: 25 mins Total Treatment: 16 weeks, every other day (indefinite)	Each treatment:18 minutes or 27 minutes Total Treatment: 16 weeks, every other day (indefinite)	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

Comparison Elements	Subject Device	Primary Predicate Device	Reference device I	Remark
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

7. 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 Neuhat Hair Growth System (or ibeauty.com 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 2020", 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 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 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
- IEC 60601-2-57 Medical Electrical Equipment-Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use
- IEC 62471 Photobiological Safety of Lamps and Lamp Systems
- IEC 60825-1 Safety of laser products-Part 1: Equipment classification, and requirements

3) Summary

Based on the above performance as documented in this application, Neuhat Hair Growth System (or ibeauty.com Laser Cap) was found to have a safety and effectiveness profile that is same as the predicate device.

8. 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, Neuhat Hair Growth System (or ibeauty.com Laser Cap) is to be concluded same to its predicate devices and reference devices.