OMM Imports, Inc. D/B/A Zero Gravity
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg. 1, Southward Ruifeng Business Center
Guimiao Road
Shenzhen, 518000 China

January 16, 2019

Re: K183329
Trade/Device Name: Laser Hair Therapy
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 2, 2018
Received: November 30, 2018

Dear Rain Yip:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.01.16 13:45:29 -05'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183329

Device Name
Laser Hair Therapy /(Model: Recreo 200)

Indications for Use *(Describe)*
Laser Hair Therapy 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-4, II-1, II-2, or frontal 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.

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

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510(k) Summary

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

Date: 2018-11-02

I. Submitter

OMM IMPORTS INC DBA ZERO GRAVITY
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Moti Shenfarber (CEO)
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II. Device

Type of 510(k): Traditional
Common Name: Lamp, non-heating, for promotion of hair growth
Trade Name: Laser Hair Therapy
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

1) Predicate device

Applicant	Predicate Device	510(k) Number	Approval Date
Lexington International, LLC	HairMax LaserComb41	K142573	Dec.1, 2014
NutraLuxe MD, LLC	Nutra Stim Hair Laser Comb Model NSL-6319	K141596	Jan.8, 2015
NutraLuxe MD, LLC9	Nutra Stim Hair Laser Comb Model NSL-6318	K141588	Jan.8, 2015

2) Reference device: None

IV. Device Description

The Laser Hair Therapy is a comb-shaped low level laser therapy (LLLT) device that emits laser light with the intention to promote hair growth. The device provides distributed laser to the scalp at 655+/-5nm while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp.

The Laser Hair Therapy is designed as handheld product, and it consists of the power supply (adaptor and USB cable) and the control unit (RECREO device), as well as it is powered by the built-in rechargeable lithium battery. The device is one-button operated, and has an audible timer that automatically turns the lasers off after the 8 minutes treatment is completed.

V. Indications for Use

Laser Hair Therapy 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-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.

VI. Comparison of Technological Characteristics With the Predicate Device

The subject device Laser Hair Therapy is substantially equivalent to the predicated device based on intended use, design, specifications and performance. The subject device 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 1	Predicate Device 2	Predicated Device 3	OAP Devices (General)
K Number	Pending	K142573	K141596	K141588	/
Product Code	OAP	OAP	OAP	OAP	OAP
Classification	Class II	Class II	Class II	Class II	Class II
Location for Use	OTC	OTC	OTC	OTC	OTC or Rx or both
Intended Use	Androgenic alopecia	Androgenetic Alopecia	Androgenetic Alopecia	Androgenetic Alopecia	Androgenetic Alopecia
Type of Laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes
Light Class	Class 3R	Class 3R	Class 3R	Class 3R	Class 3R
Amount of Laser Diodes	12	41	12	12	Ranges from 1 to 352
Energy of Per Laser Diode	<5mW	<5mW	<5mW	<5mW	Ranges (each) from less than 5mW
Wavelength	655+/-5	655+/-10	655+/-10	655+/-10	Range from

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicated Device 3	OAP Devices (General)
(nm)					635 to 678
Treatment Time	8 minutes per treatment 3 times per week (every other day)	30seconds at each of 6 positions on the scalp 3-4 times/week (every other day)	8 minutes per treatment 3 times per week (every other day)	8 minutes per treatment 3 times per week (every other day)	Frequency: every other day The specific treatment time depends on the product design. (Indefinite)
Applicable People	Norwood-Hamilton IIa~V (males) Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Norwood-Hamilton IIa~V (males)	Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Norwood-Hamilton IIa~V (males) Ludwig-Savin I-II, or frontal (females) Or both genders
Applicable Skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Appearance Design	Comb	Band	Comb	Comb	Helmet/Cap, Comb, Brush or Panel and other designs
Safety Features	Complied with: IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60825-1	Complied with: IEC60601-1-2 IEC60601-1 IEC60825-1	Complied with: IEC60601-1-2 IEC60601-1 IEC60825-1	Complied with: IEC60601-1-2 IEC60601-1 IEC60825-1	(General) Complied with IEC60601-1, IEC60601-1-2.
Biological Features	Complied with: ISO10993-5 ISO10993-10	Unknown	Complied with: ISO10993-5 ISO10993-10	Complied with: ISO10993-5 ISO10993-10	All materials of patient-contacting components should comply with the requirements

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Predicated Device 3	OAP Devices (General)
					of ISO 10993-1, and at least comply with ISO 10993-5 and ISO 10993-10.

The more details please refer to the Substantial Equivalence Discussion section in this submission.

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 Laser Hair Therapy 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 built-in battery to IEC 62133.

Summary

Based on the above performance as documented in this application, Laser Hair Therapy was found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. Conclusions

OMM IMPORTS, INC. D/B/A ZERO GRAVITY found the Laser Hair Therapy is to be substantially equivalent to the legally marketed predicate devices.