DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2016

Nutra Luxe MD LLC
Ms. Gloria Avendano
Regulatory Affairs Manager
12801 Commonwealth Drive, Unit 2-6
Fort Myers, Florida 33976

Re: K160728
Trade/Device Name: Nutrastim Hair Laser Helmet
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 18, 2016
Received: August 18, 2016

Dear Ms. Avendano:

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. 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 Part 803); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christopher J. Ronk -S

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)*
K160728

Device Name
NutraStim Hair Laser Helmet

Indications for Use *(Describe)*
NutraStim Hair Laser Helmet is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of 11a to V patters of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale 1-4, 11-1, 11-2, or frontal, both with Fitzpatrick Skin Types I to 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary
NutraStim Hair Laser Helmet

1. General Information

Submitter: NutraLuxe MD, LLC
Address: 12801 Commonwealth Dr. Unit 2
Fort Myers, FL 33913
Contact Person: Gloria Avendano
Regulatory Affairs Manager
Telephone: 239-208-7541
E-mail: Gloria@nutraluxemd.com

Summary Preparation Date:

2. Device

Device Name: NutraStim Hair Laser Helmet
Common or usual name: Lamp, non-heating, for promotion of hair growth
Classification Name: Infrared lamp per 21 CFR 890.5500
Classification Code: OAP (Laser, comb, hair)

3. Predicate Devices:

NutraStim Hair Laser Helmet is substantially equivalent to the following predicate devices;

Device	510(k) Number	Manufacturer
Sunetics Clinical Laser "G" or "W2326"	K132646	Sunetics International
Hairmax Laser Comb 82	K142573	Lexington International

Reference devices:

Device	510(k) Number	Manufacturer
LH80 Pro Laser Helmet	K122950	Theradome Inc.
MEP-90 Hair Growth Stimulation System	K091496	Midwest RF LLC
Capillus 82	K151516	Capillus LLC

4. Intended Use/Indications for Use:

NutraStim Hair Laser Helmet is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat androgenetic alopecia, and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.

5. **Technological Characteristics:**

NutraStim Hair Laser Helmet is a low-level laser device and is intended/indicated for over- the –counter use. The device emits laser light with the intention to promote hair growth. The device provides timed treatments of distributed laser light to 100% of the scalp at 650 +/- 5 nanometers. The lasers are configured inside a helmet, designed for hands-free operation during treatment. The helmet is for portable use with rechargeable battery and adapter.

6. **Performance Data**

Testing to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11confirms the device adherence to safety and EMC requirements. Testing to IEC 60825-1 certifies the laser system to classification 3R, same as predicate and referenced devices.

Lay user and Self-selection studies

A lay-user study and self-selection study was conducted with Institutional Review Board (IRB) approval and oversight to determine if lay users could read the product labeling and then self-assess if the laser helmet would be beneficial for them to use. Study data was collected and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended. The performance data supplied in this 510(k) demonstrated that the vast majority of lay users were able to properly self-select themselves using the box labeling and lay users were able to properly use the device by reading instructions in the user manual without any assistance.

In summary, the conclusion was that an average lay user can read and comprehend correctly the user manual and package labeling.

7. **Nonclinical Performance Data:**

Performance testing was conducted and confirm compliance to design specifications; similar wavelength, output power, energy type, laser field, treatment areas and energy delivery as predicate and referenced devices.

8. **Substantial equivalence**

NutraStim Hair Laser Helmet is substantially equivalent to other hair laser therapy devices currently in commercial distribution. NutraStim Hair Laser Helmet has the same intended use as the predicate devices: Treat androgenetic alopecia with red low level laser light classification 3 R. NutraStim Hair Laser Helmet delivers treatment to the entire scalp for hands-free operation during treatment and has same treatment schedule as the predicate and referenced devices. NutraStim Hair Laser Helmet shares the same indication for treating both male and female as K142573 (Hairmax 82) and K132646 (Sunetics Clinical Laser “G”). NutraStim Hair Laser Helmet is as safe and (commensurate to number of diodes) effective as its predicate and referenced devices. NutraStim Hair Laser Helmet has 650 +/- 5nm wavelength and similar output to the treatment area as the predicate and referenced devices. Thus, NutraStim Hair Laser Helmet is substantially equivalent to legally marketed medical devices.

Comparison Table

Comparative Item	NutraStim Hair Laser Helmet	Sunetics Clinical Laser "G"	Capillus 82	Hairmax 82	LH80 PRO	MEP 90
510 (k) Number	k160728	K132646	K151516	K142573	K122950	K091496
Product Code	OAP	OAP	OAP	OAP	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Device Type	Portable helmet, sits on patient's head, spherical laser helmet.	Free Standing, movable laser helmet, spherical laser helmet	Portable helmet, sits on patient's head, spherical laser helmet.	Portable helmet, sits on patient's head, spherical laser helmet.	Portable helmet, sits on patient's head, spherical laser helmet.	Free Standing, movable laser helmet, spherical laser helmet
Indications for Use	Indicated to treat Androgenetic Alopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.	Indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV and also in Females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.	Indicated to promote hair growth in females who have androgenetic alopecia and Ludwig-Savin Classifications of I-11; and with Fitzpatrick Classifications of Skin Phototypes I to IV.	Indicated to treat Androgenetic Alopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.	Intended to treat Androgenetic Alopecia to promote hair growth in females with female pattern hair loss (FPHL) on the Ludwig and Savin Hair Loss scale I-II, Fitzpatrick Skin Types I to IV.	Intended for the treatment of alopecia in females by promoting hair growth of females with androgenetic alopecia who have Ludwig and Savin Hair Loss Scale classifications of I to II and who have been determined to have Fitzpatrick Skin Typing of I to IV.
Number of Laser Diodes	82	107	82	82	80	82
Wavelength (nanometer)	650 +/- 5	650 +/- 5	650 +/- 5	650 +/- 5	678	650 +/- 5
Output (Per diode)	5 mW	5 mW	5 mW	5 mW	5 mW	5 mW
Laser Classification	Class 3R	Class 3R	Class 3R	Class 3R	Class 3R	Class 3R
Treatment Protocol	20 Minutes- 3 times a week	20 minutes- 3 times a week	30 minutes- 3 times a week	90 seconds- 3 times a week	20 minutes- 3 times a week	20 minutes- 3 times a week
Standards Applied	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60825-1 ISO 14971	IEC 60601-1 IEC 60601- 1-2 IEC 60825-1	IEC 60825-1 ISO 14971	IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1
Device Class	Class II	Class II	Class II	Class II	Class II	Class II
Accessories	Medical Grade Power Cord	Medical Grade Power Cord	Medical Grade Power Cord	Medical Grade Power Cord	Medical Grade Power Cord	Medical Grade Power Cord
Common Name	Lamp, Non-Heating	Lamp, Non-Heating	Lamp, Non-Heating	Lamp, Non-Heating	Lamp, Non-Heating	Lamp, Non-Heating

9. Conclusion:

Based upon the indications for use and data provided in this pre-market notification, all functional modes of the NutraStim Hair Laser Helmet have been shown to be substantially equivalent to current marketed predicate and referenced devices with respect to intended use, technological characteristics and safety characteristics. NutraLuxe MD believes that no significant differences exist between the device and the predicates. Therefore, Substantial equivalency is requested.