DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 8, 2015

NutraLuxe MD, LLC
% Jill Cleasy
Regulatory and ISO Consulting
5575 Santa Rosa Court
Sparks, Nevada 89436

Re: K141588
Trade/Device Name: Nutra Stim Hair Laser Comb Model NSL-6318
Regulation Number: 21 CFR 890.5500
Regulatory Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 03, 2014
Received: December 09, 2014

Dear Ms. Cleasy:

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 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 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" (21CFR 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,

David Krause -S

for Binita 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

cc: Enclosed

Indications for Use

510(k) Number (if known): _K

Device Name: ***Nutra Stim Laser Comb***

Indications for Use:

The Nutra Stim Hair Laser Comb is indicated to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, LL-1, LL-2, or frontal and Fitzpatrick Skin Types L to IV.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510K Summary
Nutra Stim Hair Laser Comb

1. General Information

Submitter:

NutraLuxe MD, LLC
6835 International Center Blvd Suite 4-5
Fort Myers, Florida 33912

Contact Person:

C/O Jill Creasy
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Summary Preparation Date: June 13, 2014

2. Device Name

Device Name: ***Nutra Stim Hair Laser Comb Model NSL-6318***

Regulatory Name: Lamp, nonheating, for promotion of hair growth

Regulation Numbers: 21 CFR 890.5500

Regulatory Class: II

Product Codes: OAP

3. Predicate Device

The ***Nutra Stim Hair Laser Comb*** is substantially equivalent to the HairMax Pro 12 LaserComb (K112524)

4. Device Description

The ***Nutra Stim Hair Laser Comb*** is a hand-held low level laser device that emits laser light with the intention to promote hair growth. The device provides distributed laser light to the scalp while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp.

The Nutra Stim Hair Laser Comb unit contains the power supply, internal NI-MH rechargeable battery and the control unit. The enclosure and laser lens are made of medical grade biocompatility plastics via injection molding. The STOP button directly on the unit allows the user to immediately remove all power to the unit. The Nutra Stim Hair Laser Comb does not use any software.

5. Intended Use and Indications:

The ***Nutra Stim Hair Laser Comb*** is indicated to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, LL-1, LL-2, or frontal and Fitzpatrick Skin Types L to IV.

6. **Substantial Equivalency & Comparison of Technological Similarities and Differences**

The Nutra Stim Hair Laser Comb are as safe and effective as the predicate device. The Nutra Stim Hair Laser Comb have the same indications, (i.e., treating androgenetic alopecia, promote hair growth in females who have Ludwig (Savin) Scale I-4, LL-1, LL-2, or frontal and Fitzpatrick Skin Types L to IV, as the predicate device.

The Nutra Stim Hair Laser Comb are identical in technological characteristics as the predicate, including its laser power, wavelength, laser delivery method, its comb component, its instructions for use and its audible timer.
The Nutra Stim Hair Laser Comb have the following similarities to the HairMax Pro

1. Has the same indicated use
2. Same identical laser modules
3. Similar hair parting teeth
4. Uses the same operating principle
5. Similar device design and physical properties
6. Incorporates the same materials
7. Utilizes a same treatment duration
8. Utilizes a similar treatment regimen

Any differences between ***The Nutra Stim Hair Laser Comb*** and the predicates device are not significant to its safety or effectiveness for its intended use.

7. **Clinical Performance Data**

An OTC Usability Study was conducted with the following four goals in mind 80 participants;
1. To attract participants that represented the "intended users" of the device;
2. To determine if consumers could correctly self-select using the packaging labeling only
3. To test consumer knowledge of the packaging labeling and user manual and actually assembly, operate and care for the device correctly. All four goal of the study were met

8. Nonclinical Performance Data

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 10
The Nutra Stim Hair Laser Comb device was also tested and complies with Electrical Safety and EMC testing, which include the requirements of IEC 60601-1:2012 3rd Edition "Medical Electrical Equipment Part 1 – General Requirements for Safety" IEC 60601-1-2 "Medical Electrical Equipment Part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility Requirements and Tests IEC 60601-1-11 Home healthcare medical equipment and IEC 60825 Safety of laser products - Part 1: Equipment classification and requirements. In addition, testing and analysis have demonstrated compliance of the plastic within ISO 10993 (Biocompatibility).

9. Regulatory Requirements

NutraLuxe MD manufactures under strict quality assurance guidelines and US FDA Good Manufacturing Practice (GMP)
Nutra Luxe MD is fully compliant with 21 CFR Part 820, US FDA Quality Systems Regulations (QSR), Risk Analysis and Risk Management files (RMF) conforms to ISO 14971,

Conclusion: Nutra Luxe MD, Inc. found ***The Nutra Stim Hair Laser Comb*** device to be substantially equivalent to the legally marketed predicate devices.