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

August 22, 2017

Leana Orders, Inc.
% Raymond Blanche
Managing Member
NST Consulting, LLC
641 Shunpike Road
Chatham, New Jersey 07928

Re: K171895
Trade/Device Name: Grivamax Hair Growth System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: June 1, 2017
Received: June 26, 2017

Dear Raymond Blanche:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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)*
K171895

Device Name
GrivaMax Hair Growth System

Indications for Use *(Describe)*

The GrivaMax Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I-II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications IIa-V and for both, Fitzpatrick Classification of Skin Phototypes of 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Leana Orders, Inc.

Submitter's Contact Information

Name:	Raymond R. Blanche
Address	NST Consulting, LLC 641 Shunpike Road, Suite 311 Chatham, NJ 07928
Telephone: Facsimile:	(973-539-7444 (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name:	Grivamax Hair Growth System
Sponsor Contact Information:	Leonid Krits Leana Orders, Inc. 431 Travis Avenue Staten Island, NY 10314-6150
Telephone:	718-415-1901

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)

Predicate Devices:

Device Trade Name	Manufacturer
Illumiflow Laser Cap	Cosmo Far East Technology Limited

Reference Devices:

None

Date Prepared: August 17, 2017 Revised

Intended Use / Indications for Use

The Grivamax Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II, males who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.

Technological Characteristics

The Grivamax Hair Growth System consists of 272 diode lasers configured within an outer cap helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head i.e., the area commonly covered with stylized hair. The Grivamax Hair Growth System is powered by a lithium-ion battery pack that contains an embedded controller chip.

Performance Data:

No clinical performance data was produced for this submission because the Grivamax Hair Growth System is the same device as the predicate, the Illumiflow Laser Cap, cleared under K162071. Both the Grivamax Hair Growth System and Illumiflow Laser Cap are the IDENTICAL same device offered for PRIVATE LABEL by the manufacturer, Cosmo Far East Technology Limited. They are the same device in optical, electronic, mechanical function and aesthetic appearance, as well as the same recommended clinical treatment regime.

Substantial Equivalence

Both the Grivamax Hair Growth System and Illumiflow Laser Cap which use red light diode lasers are classified as class IIIa/3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same. The sponsor believes that there is no difference in the physical appearance or in the method of delivering the radiant energy of the two systems and therefore, there are no variations in the therapeutic value or safety profile.

Finally, the summarized data contained in the Illumiflow Laser Cap in the 510(k) notice confirms the safety and efficacy of the device and accordingly, of the proposed Grivamax Hair Growth System for Over-the-Counter Use per Part 21 CFR 801 Subpart C. For these reasons, the Grivamax Hair Growth System overwhelmingly satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

Treatment Protocol

The Grivamax Hair Growth System and the Illumiflow Laser Cap igrow devices possess the same treatment regime of 30 minutes, every other day, on non-consecutive days, for the initial treatment regime of 16 weeks.

The following Comparison Chart in support of substantial equivalence is provided:

Grivamax Hair Growth System	**Illumiflow Laser Ca**p
LLLT Device Type	Identical
OTC Application	Identical
Intended Use - Androgenetic Alopecia	Identical
Contain Laser Diodes-272 Class 3R	Identical
Helmet Design	Identical
650+/-5 NMS.	Identical
Marketing Clearance –Females & Males, OTC	Identical
Passive Use-Hands Free	Identical
OAP Classification	Identical
Classification Name -Infrared Lamp	Identical
Common Usage Name - Lamp, Non-Heating	Identical
General & Plastic Surgery Committee	Identical
Skin Phototypes - I- IV	Identical
Hamilton-Norwood IIa-V Hair Loss Classification Ludwig-Savin I – II Hair Loss Classification	Identical Identical
Efficacy Rates - High Compared to Placebo	Identical
Treatment- 16 weeks, every other day, for 30 minutes per session	Identical
Device Class II	Identical

With the data presented in the Comparison Chart, the sponsor believes that this data demonstrates that the two devices are identical and equivalent, PRIVATE LABEL devices from the same manufacturer and therefore are identical because the manufacturer ONLY produces one device.

Based on this comparison and determination, the sponsor requests the FDA to clear the device via the 510(k) notice.

Over – The – Counter Testing Program

To test volunteer subjects for the suitability of the Grivamax Hair Growth System, 40 subjects were asked twenty-six questions (see questionnaires) after being provided a standard retail package and a full owner's manual. The test subjects was given as long as they required to read and understand the product packaging and manual. No assistance was provided to them and they were not permitted to ask any questions of the interviewer. The interviewer then conducted the interview and filled in the responses

from the subjects. The subjects were required to answer all questions correctly to be counted as PASS for the correct Self Selection or, to have made the correct decision to purchase the product or not; to assemble and use the product correctly and comprehend the hazards and maintenance procedures for the device. These decisions would be based upon their understanding of the Intended Use of the product and the manual.

If the questions were answered correctly, they were given a P for PASS. If any questions were answered incorrectly, they were given an F for FAIL. The number of subjects required to answer all questions correctly is 32 out of 40, for an 80% success rate.

The results of the Over-the-Counter testing demonstrate that the **Grivamax Hair Growth System** complies with the requirements the FDA determined to be applicable. The test revealed an overall **90% pass rate** for the subject group of 40 male and female participants. The testing further demonstrates that age, education, socioeconomic group, race or medical hair loss status are not variants that prevent proper self-selection, usability and comprehension of hazards and maintenance procedures for the average consumer to successfully navigate the purchasing and use process of the **Grivamax Hair Growth System.**

Based on this data, the sponsor believes that the **Grivamax Hair Growth System** for male and female users should be granted the OTC intended use as requested.

Electrical Safety and Electromagnetic Compatibility Testing Performance

The Grivamax Hair Growth System was evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

1. IEC 60825-1 Edition 2.0 2007-03 Safety of Laser Products – Part 1: Equipment Classification and Requirements.
2. IEC 60601-1-2 Edition 3.0 2007-03 Medical Electrical Equipment – Part 1-2 General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Part 1: Requirements and Tests.