July 20, 2021

Leana Orders, Inc
℅ Raymond Blanche
Consultant
NST Consultants, Inc.
5 Cold Hill Road South, Unit 12
Mendham, New Jersey 07945

Re: K211192
Trade/Device Name: Grivamax Family of Lasers, Models 272 and 148
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 17, 2021
Received: April 21, 2021

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. 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,

Purva Pandya
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

Section 4

Indications for Use Statement

FDA Form 3881

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)*

K211192

Device Name
Grivamax Family of Lasers, Models 272 and 148

Indications for Use *(Describe)*
The Grivamax Family of Lasers , Models 272 and 148 are 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.

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.

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510(k) Summary for K211192

Leana Orders, Inc.

Submitter's Contact Information

Name:	Raymond R. Blanche
Address	NST Consultants, Inc 5 Cold Hill Road South Unit 12 Mendham, New Jersey 07945
Telephone:	(973)531-6226
Facsimile:	(973)539-7445

Name of Device and Name/Address of Sponsor

Trade Name:	Grivamax Family of Lasers, Models, 272 and 148
Sponsor Contact Information:	Leonid Krits Leana Orders, Inc. 12 Jefferson Boulevard Suite 1F Staten Island, NY 10312
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
Diode Laser Cap (K173678)	Cosmo Far East Technology Limited
Grivamax Hair Growth System (K171895)	Cosmo Far East Technology Limited

Reference Devices:

None

Date Prepared: July 20, 2021 Revised

Intended Use / Indications for Use

The Grivamax Family of Lasers, Models, 272 and 148 are 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 Family of Lasers, Models 272 and 148 consist of 272 diode lasers or 148 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 Family of Lasers, Models 272 and 148 are 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 Family of Lasers, Models 272 and 148 are the same device as the Cleared predicates, the Diode Laser Cap (K173678) and the Grivamax Hair Growth System(K171895). Both predicates are IDENTICAL devices 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 proposed devices, of which the Grivamax Hair Growth System is Cleared under (K171895) and the Diodes Laser Cap, Cleared under (K173678) 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 Predicates and Proposed devices in the following chart confirms the safety and efficacy of the device and accordingly, the Proposed devices, Grivamax Family of Lasers, Models 272 and 148 should be granted a 510(k) Clearance for Over-the-Counter Use per Part 21 CFR 801 Subpart C. For these reasons, the Grivamax Family of Lasers, Models 272 and 148 overwhelmingly satisfy the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

Treatment Protocol

The Grivamax Family of Lasers, Models 272 and 148 and the Diode Laser Cap 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:

Specification Category	**Grivamax Family of Lasers Models 272 and 148** (K211192)	**Diode Laser Cap** (K173678) **Grivamax Hair Growth Lasers** (K171895) **Models 272 and 148**
	Proposed Device for OTC Use	**Predicate with OTC Indication for Use**
LLLT Device Type	Laser Diode	Laser Diode
Use Application	OTC	OTC
Intended Use Androgenetic Alopecia	Androgenetic Alopecia	Androgenetic Alopecia
Contain Laser Diodes-Class 3R	272, 148, 5 milliwatts each.	272, 148, 5 milliwatts each.
Physical Design of Device	Helmet	Helmet
Wavelength	650+/-5 NMS.	650+/-5 NMS.
Marketing Clearance	For females and males, OTC	For females and males OTC
Use Type	Passive Use-Hands Free	Passive Use-Hands Free
Classification Code	OAP	OAP
Classification Name	Infrared Lamp	Infrared Lamp
Common Usage Name	Lamp, Non-Heating	Lamp, Non-Heating
Classification Panel	General & Plastic Surgery	General & Plastic Surgery
Skin Phototypes	I- IV	I- IV
Hair Loss Classification	Hamilton-Norwood IIa-V for males Ludwig-Savin I – II for females	Hamilton-Norwood IIa-V for males Ludwig-Savin I – II Hair for females
Treatment Regime	16 weeks, for 30-minute treatment times three times a week, on alternate days.	16 weeks, for 30-minute treatment times three times a week, on alternate days.
Device Class	II	II

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

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

No OTC testing was performed for this submission because the User Manual and packaging contents for the predicates. While some of the language contained in the User Manuals of the Proposed devices may differ, these differences do not alter the Self Selection, Hazards and Precautions, or Usability criteria. The only major exception is color and logo of the subject device literature. The graphic changes do not alter the content of the User Manual, the key variable in any OTC testing evaluation. The aesthetic appearance of the proposed devices, the predicates devices and the reference devices all use the same exterior black shell and interior clear shells. The dimensions of the shells are also equivalent.

Electrical Safety and Electromagnetic Compatibility Testing Performance

The Grivamax Family of Lasers, Models 272 and 148 were not evaluated for conformance to recognized international standards.
Biocompatibility, electrical safety and EMC testing is not needed in this submission because the subject device is identical to the predicate devices in these aspects.

Shelf Life

The Usable life expectancy for this device is 10,000 hours based on the specifications for the laser diode and 5 years for the overall usable life of the Grivamax Family of Lasers, Models 272 and 148

Electrical Safety Testing Performance

The Grivamax Hair Growth System and Diode Laser Cap were 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 3.0 2014 Safety of Laser Products – Part 1: Equipment Classification and Requirements.
2. IEC 60601-1-2-22 Edition 3.1 2012-10 Basic Safety and Essential Performance

Conclusion

Based on the technical comparisons between the Grivamax Hair Growth Lasers (K171895) and the Diode Laser Cap (K173678) which are the same as the Proposed devices, it can be concluded that the proposed devices are substantially equivalent to the predicate devices in technical specifications. Since the proposed devices are currently being marketed with an OTC Indication for Use, therefore, with no modifications in manufacturing, the proposed devices and predicates do not raise any issues of safety or efficacy.

The summary includes the conclusions drawn from the nonclinical and clinical tests ((discussed above) that demonstrate that the devices are as safe and as effective and perform as well as or better than the predicate devices.