June 20, 2018

Lexington International, LLC
% Raymond Blanche
Consultant
NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

Re: K180885
Trade/Device Name: HairMax Laser Model 272, Model 202, and Model 80
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 19, 2018
Received: April 4, 2018

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180885

Device Name
HairMax Laser Laser 272, 202, and 80

Indications for Use *(Describe)*
The HairMax Laser 272, 202 and 80 are indicated to promote hair growth in males with androgentic alopecia who have Norwood-Hamilton Classifications of IIa - V, or females with androgenetic alopecia who have Ludwig-Savin Classifications I - II or Frontal and for 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.

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510(k) Summary

Revised June 19, 2018

Lexington International, LLC

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:	HairMax Laser 272, 202 and 80
Sponsor Contact Information:	David Michaels Lexington International, LLC 1040 Holland Drive Boca Raton, Florida 33487 Telephone: 561-417-0200
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
Capillus 202 K163170	Capillus, LLC
Lasercap 80 K161875	Transdermal Cap, Inc.

Reference Devices:

Illumiflow Laser Cap Cosmo Far East Technology Limited

Date Prepared: February 19, 2018

Intended Use / Indications for Use

The HairMax Laser 272, 202 and 80 are indicated to promote hair growth in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa – V, females who have Ludwig-Savin Classifications of I – II or Frontal and for both, Fitzpatrick Skin Phototypes I to IV.

Technological Characteristics

The HairMax Laser 272, 202 or 80 each contain the listed number of 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 HairMax Laser 272, 202 and 80 are powered by a lithium-ion battery pack that contains an embedded controller chip. In all other area of design, manufacturing, and aesthetic appearance, the devices are identical.

Performance Data:

No clinical performance data was produced for this submission because the HairMax Laser 272, 202 and 80 are the same device as the predicate, the Diode Laser, cleared under K173678, the Capillus 202, cleared under K163170 and the Lasercap 80, cleared under K161875. All proposed devices and predicate devices are IDENTICAL and the same devices offered for PRIVATE LABEL by the manufacturer. They are the same device in optical, electronic, mechanical function and aesthetic appearance, as well as the same recommended clinical treatment regime. It is essential to understand that this class of device is manufactured by many different manufacturers, all using the same parts supplied by the same OEM suppliers. Hence, there are virtually no differences between the devices.

Substantial Equivalence

Both the HairMax Laser 272 and the Diode laser 272 use red light diode Lasers, 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.

For these reasons, the HairMax Laser 272 overwhelmingly satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

The HairMax Laser 202 and 80 are prospective devices that will be manufactured by an ISO 13485 compliant contract manufacturer, on the same platform as the Hairmax Laser 272. There are no safety concerns raised by this process of manufacturing because the model 272 contains the largest number of laser diodes, obviating the requirement for electronic heat analysis for the lesser diode laser models, the 202 and 80.

Treatment Protocol

The HairMax Models 272, 202 and 80 the identified predicates, 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:

HairMax Laser 272, 202 and 80	**Diode Laser 272**	**Capillus 202**	**Lasercap 80**
LLLT Device Type	Laser diode	Laser Diode	Laser Diode
Use Application	OTC	OTC	Rx
Intended Use - Androgenetic Alopecia	Yes	Yes	Yes
Contain Laser Diodes-Class 3R	Yes 272	Yes 202	Yes 80
Helmet Design	Yes	Yes	Yes
650+/-5 NMS.	Yes	Yes	Yes
Marketing Clearance –Females & Males, OTC	Yes	Yes	Females Only Rx
Passive Use-Hands Free	Yes	Yes	Yes
OAP Classification	Yes	Yes	Yes
Classification Name -Infrared Lamp	Yes	Yes	Yes
Common Usage Name - Lamp, Non-Heating	Yes	Yes	Yes
General & Plastic Surgery Committee	Yes	Yes	Yes
Skin Phototypes - I- IV	Yes	Yes	Yes
Hamilton-Norwood IIa-V Hair Loss Classification Ludwig-Savin I – II Hair Loss Classification	Yes Yes	Yes Yes	Yes Yes
Efficacy Rates - High Compared to Placebo Identical	Yes	Yes	Yes
Treatment- 16 weeks, for 30 minute treatment times three times a week on alternate days.	Yes	Yes	Yes
Device Class II	Yes	Yes	Yes

The data presented in the Comparison Chart, demonstrates that all three HairMax models 272 devices are identical and equivalent, PRIVATE LABEL devices from the same manufacturer are identical and equivalent, PRIVATE LABEL devices. The Models 202 and 80 will be manufactured on the same platform by the same manufacturer as the 272.

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 HairMax Laser 272, 202 and 80, 40 subjects were asked twenty-six questions, 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 HairMax Laser 272, 202 and 80 comply 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 HairMax Laser 272, 202 and 80**.**

Based on this data, the sponsor believes that the Hairmax Laser 272, 202 and 80 for male and female users have met the requirements for OTC sale.

Electrical Safety and Electromagnetic Compatibility Testing Performance

The HairMax Laser 272, 202 and 80 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.

Conclusion

Based on the technical comparisons between the HairMax 272, 202 and 80 and the identified predicates it can be concluded that the HairMax Models are identical to the predicate devices in technical specifications. Since the Hairmax Models are built using the identical platform with the only difference between models being the number of didoes, it can be concluded that all of the HairMax models are equally safe. Therefore,, it can be determined that the HairMax Model 272, 202 and 80 are Substantially Equivalent to the identified predicates.