Lexington International, LLC

AUG 16 2011

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Lexington International, LLC HairMax Dual 12 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Lexington International, LLC
777 Yamato Rd. Suite 105
Boca Raton, FL 33431
(561) 417-0200
research@hairmax.com

Contact: Olsson Frank Weeda
C/O Casper E Uldriks Esq.
1400 Sixteenth Street, NW
Washington DC 20036

Date of Submission: June16, 2011

Proprietary Name: HairMax Dual 12

Common Name: Lamp, non-heating, for promotion of hair growth

Regulatory Class: II

Product Codes: OAP

Predicate Device(s): Lexington International, LLC - HairMax Lux 9 and HairMax Pro 12 (K103368) and Female Lux 9 (K110233)

Device Description:

Substantially equivalent to the HairMax Pro 12 (K103368) and HairMax Lux 9 for females (K110233), the HairMax Dual 12 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 maximum laser light reaches the user's scalp. HairMax Dual 12 utilizes twelve laser modules, six with wavelengths of 655nm and six with wavelengths of 635nm with the same exact output power as the HairMax Pro 12.

Intended Use:

The HairMax Dual 12 is indicated to Treat Androgenetic Alopecia and Promote Hair Growth in Females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal and Fitzpatrick Skin Types I to IV.

Technological Characteristics

The HairMax Dual 12 consists of a hand-held low-level laser device that promotes hair growth. The device provides distributed laser light to the scalp while the device's comb teeth simultaneously part the user's hair to ensure maximum laser light reaches the user's scalp. When in use, the device emits a beep and vibration every four seconds to notify the user to move the device to a new section of the scalp.

Performance Testing

Testing to IEC 60601-1 and 60601-1-2 confirm the device's adherence to LVD electrical and EMC safety requirements.

Clinical Testing

A randomized, double-blind, controlled, multi-center clinical trial was conducted at 3 sites, Cleveland Clinic – Wilma Bergfeld M.D., University of Minnesota – Maria Hordinsky M.D. and University of Miami – Lawrence Schachner M.D. Each site complied with Institutional Review Board approval and oversight and in accordance with applicable references defined by the Food and Drug Cosmetics Act and Title 21, Code of Federal Regulations. The clinical trials were listed on www.clinicaltrials.gov. The purpose of the clinical trial was to confirm the performance of the HairMax Dual 12 to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal and Fitzpatrick Skin Types I to IV.

After 16 weeks of treatment, 81% of the subjects using the HairMax Dual 12 experienced increases in hair count, (based on a minimum of 5 new hairs being observed at follow up). Benefits continued to improve after 26 weeks of treatment, 95% of the subjects using the HairMax Dual 12 experienced significant increases in hair count (based on a minimum of 5 new hairs being observed at follow up). No

subjects experienced any serious adverse event from the treatments.

The study population included females between the ages of 25 to 60 years with a diagnosis of androgenetic alopecia who had been experiencing active hair loss within the last 12 months. They were also required to have a Ludwig (Savin) classification of I-4, II-1, II-2 or Frontal, and have Skin Type I, II, III, or IV on the Fitzpatrick Skin Type Scale. Skin types were limited to the Fitzpatrick Skin types I-IV to facilitate the hair counting process, as it is difficult to count hairs on darker skin tones.

Substantial Equivalence

The HairMax Dual 12 is as safe and effective as the predicate devices. The HairMax Dual 12 has the same intended use of promoting hair growth as the predicate devices. The subject device has the same general indications, *i.e.*, treating androgenetic alopecia and promoting hair growth.

The HairMax Dual 12 is identical in technological characteristics as the HairMax Pro 12 as cleared in K103368 and HairMax Lux 9 for females (K110233), except for the dual wavelength component. The HairMax Pro 12 contains twelve 655nm laser modules, the HairMax Dual 12 contains six 655nm laser modules and six 635nm laser modules. All other technical aspects, including its power output, its comb component, its instructions for use and its audible or vibrating timer remain identical. The modification to the HairMax Dual 12 does not change the intended use of the product nor does it affect the products fundamental scientific technology. Therefore this change does not raise new questions of safety or effectiveness. This was also demonstrated in a randomized, double-blind, control clinical study evaluating changes in terminal hair-count in the evaluation zone, as well as usability studies to validate instructions for use, confirm that device modifications do not affect the safe and effective use of the devices when compared to the predicates.

For those reasons, HairMax Dual 12 satisfies FDA's substantial equivalence with respect to both the intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Lexington International, LLC
% Olsson Frank Weeda
Casper E. Uldriks, Esq.
1400 Sixteenth Street, NW
Washington, District of Columbia 20036

Re: K111714
Trade/Device Name: HairMax Dual 12
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: June 16, 2011
Received: June 20, 2011

AUG 16 2011

Dear Mr. Uldriks:

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.

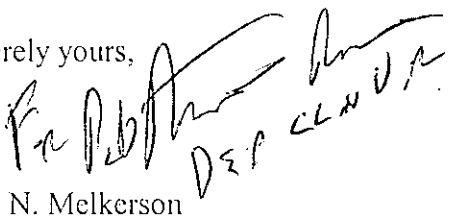
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: k111714

Device Name: HairMax Dual 12

Indications for Use:

The HairMax Dual 12 is indicated to Treat Androgenetic Alopecia and Promote Hair Growth in Females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal and Fitzpatrick Skin Types I to IV.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number k111714