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
% Olson Frank Weeda
Casper E. Uldriks, Esq.
1400 Sixteenth Street, NW
Washington, District of Columbia 20036

MAY 27 2011

Re: K110233
Trade/Device Name: HairMax LaserComb Lux 9
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: May 24, 2011
Received: May 25, 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,

Erin D. Keith

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

Enclosure

**Section 5: 510(k) Summary:**

The following information is provided as required by 21 CFR § 807.87 for Lexington International, LLC HairMax LaserComb Lux 9 510(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
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(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:** January 21, 2011

**Proprietary Name:** HairMax LaserComb Lux 9

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

**Regulatory Class:** II

**Product Codes:** OAP

**Predicate Device(s):** Lexington International, LLC HairMax LaserComb (K060305 & K093499)

**Device Description:**

Substantially equivalent to the HairMax LaserComb Premium (K060305, K093499), the HairMax LaserComb Lux 9 is a hand-held low-level laser devices 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 Lux 9 replaces the cleared version's single beam laser and beam splitting reflector with a circuit board containing nine laser modules.

**Intended Use:**

The HairMax LaserComb Lux 9 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 LaserComb Lux 9 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. Testing to IEC 60825 confirm the laser classification to be Class 3R, same as the predicate devices.

**Clinical Testing:**

A randomized, double-blind, controlled, multi-center clinical trial was conducted at 6 sites 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 LaserComb Lux 9 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, 88% of the subjects using the HairMax LaserComb Lux 9 experienced increases in hair count. Benefits continued to improve after 26 weeks of treatment, 95% of the subjects using the HairMax LaserComb Lux 9 experienced significant increases in hair count. Most of the subjects reported improvement in their hair condition which included; reduction in shedding and improved fullness and thickness of their hair. No subjects experienced

any serious adverse event from the treatments.

The study population included females between the ages of 25 and 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 LaserComb Lux 9 is as safe and effective as the predicate devices. The HairMax Lux 9 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. The difference being that the predicate devices are cleared for use to treat male androgenetic alopecia while the subject device is intended to treat female androgenetic alopecia.

Except for modifications to the laser delivery method and increase in laser output, the HairMax Lux 9 is identical in technological characteristics as the HMLC as cleared in K060305 and K093499, including its red laser wavelength, its comb component, its instructions for use and its audible or vibrating timer. The modification to the HairMax LaserComb Lux 9 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 LaserComb Lux 9 satisfies FDA's substantial equivalence with respect to both the intended use and technological characteristics.

# Section 4: Indications for Use Statement

**510(k) Number:** To be assigned K110233

**Device Name: HairMax LaserComb Lux 9**

**Indications for Use:**

**The HairMax LaserComb Lux 9 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.**

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MAM

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

510(k) Number K110233