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

December 1, 2014

Lexington International, LLC
% Mr. Evan P. Phelps
OFW Law
600 New Hampshire Avenue, NW, Suite 500
Washington, District of Columbia 20037

Re: K142573
Trade/Device Name: HairMax LaserComb 82 and HairMax LaserComb 41
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Phelps:

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 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" (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 Industry and Consumer Education 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,

FDA

David Krause -S

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)*
K142573

Device Name
Device Name: HairMax LaserComb 82 and HairMax LaserComb 41

Indications for Use *(Describe)*
The HairMax LaserComb 41 is indicated to treat Androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic alopecia and, promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.

The HairMax LaserComb 82 is indicated to treat Androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic alopecia and, promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types 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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"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

"510(k) Summary"
As required by section 807.92(c)
For
HairMax LaserComb 41 and HairMax LaserComb 82

September 11, 2014

1. Company Name and Address

    a. Sponsor/Manufacturer

    Lexington International, LLC
    777 Yamato Road
    Suite 105
    Boca Raton, FL 33431

    b. Consultant/Contact

    Evan P. Phelps
    OFW Law
    600 New Hampshire Ave, Ste. 500
    Washington D.C. 20037
    ephelps@ofwlaw.com
    Tel: (202) 789-1212
    Fax: (202) 234-3550

2. Establishment Registration Number: 3006182775

3. Device Name:

    a. Trade Name: HairMax LaserComb 41
    HairMax LaserComb 82
    b. Common/Usual Name: Lamp, Non-Heating, for Promotion of Hair Growth
    c. Classification Name: Comb, Laser, Hair

4. Device Classification:

    a. 21 C.F.R. § 890.5500 (Class II)
    b. Product Code: OAP
    c. Classification Panel: General & Plastic Surgery

5. Legally Marketed Predicate Devices:

   a. HairMax LaserComb Lux 9
      i. 510(k) Owner: Lexington International, LLC
      ii. 510(k) Number: K110233
      21 C.F.R. § 890.5500 (Class II)
      Product Code: OAP

   b. HairMax LaserComb Lux 9
      i. 510(k) Owner: Lexington International, LLC
      ii. 510(k) Number: K103368
      21 C.F.R. § 890.5500 (Class II)
      Product Code: OAP

6. Device Description

The HairMax LaserComb 41 (HMLC 41) and HairMax LaserComb 82 (HMLC 82) are low-level laser devices that provide distributed laser light to the scalp while comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. The HMLC 82 device emits 82 laser beams with wavelengths of 655 nm (+/- 10 nm), spaced at 7mm intervals and has a total laser module output within the limitation of a Class 3R laser. The HMLC 41 device emits 41 laser beams with wavelengths of 655 nm (+/- 10 nm), spaced at 7mm intervals and has a total laser module output within the limitation of a Class 3R laser. The laser diode modules used in the HMLC 41 & 82 are identical to those used in their predicate devices.

As with the predicate device, the HMLC 41 & 82's lasers are contained in between hair parting teeth that push the hair aside, allowing the optimum amount of laser energy to reach the scalp, as the user passes over the scalp. The hair parting teeth move the hair aside and allow an unobstructed path of laser energy to the scalp.

At the beginning of a treatment session, the device is placed in the first position on the scalp (the first 7.5cm scalp section, closest to the forehead) and will rest here for the intended treatment time. As with the predicate devices, the HMLC 41 & 82 will use a short vibration to advise the user it is time to move to the next scalp location. The HMLC 41 & 82 will maintain contact with the scalp allowing the hair parting teeth to part the hair as the user moves the device backwards, combing the hair, along the scalp to the second position. The teeth are necessary to part the hair and provide an unobstructed path for the laser light to reach the scalp. The device will remain in the second position until the vibration informs the user to move to the third position. Similar indication and movement will continue for three positions to cover the entire area of hair loss on the scalp. The lasers will automatically turn off after the intended treatment duration.

The units operate from an internal, rechargeable lithium polymer battery. The LiPoly battery is charged from a Class 2, UL, and CUL rated wall transformer at 6VDC and 1000mA. In the event of a power failure, the laser control circuitry is designed to disable the laser diodes until reactivated by the control switch. The devices include battery monitoring and charging circuitry which ensure the effective delivery of optimal laser energy output during the treatment time. The devices include a proximity sensor and will not allow the lasers to be turned on unless in contact with the scalp.

7. Intended Use

The intended use of the HairMax LaserComb 41 and HairMax LaserComb 82 is the same as for the HairMax LaserComb Lux 9 (HMLC Lux 9) cleared pursuant to K103368 and K110233.

The HairMax LaserComb 41 is indicated to treat Androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic alopecia and, promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.

The HairMax LaserComb 82 is indicated to treat Androgenetic alopecia and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treat Androgenetic alopecia and, promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal, both with Fitzpatrick Skin Types I to IV.

8. Technological Characteristics

The HMLC 41 & 82 are versions of Lexington's previously cleared HMLC Lux 9 that has been modified as a result of customer feedback to provide hands-free operation for ease of use. To address this issue and reduce the overall effort required by users, Lexington sought to: 1) modify the shape of the device such that it can rest on the scalp (without the need for the user to hold it in place with their hand) while maintaining the device's hair-parting teeth feature; and 2) reduce treatment time by increasing the number of lasers providing treatment over a larger surface area while maintaining dosage rate. The implemented modifications included changes to:

- Device configuration/dimensions to accommodate additional lasers and allow "hands-free" placement on the scalp;
- Addition of a second identical battery
- Conforming software changes reflecting reduced overall treatment time; and
- Addition of a proximity sensor for laser activation.

Otherwise, the modified devices have the same technological characteristics as their predicate to include operating principle, fundamental scientific technology, design, materials, and chemical composition.

9. Performance

Evidence of safety and efficacy was obtained from bench testing to support the intended use of this device to include:

- Laser Safety testing to confirm Class 3R operation per IEC60825-1:2007, Condition 1 and Condition 2
- Laser output parameters and dose rate were verified against the predicate device using Ophir 7Z01560, Serial # 544640 with a last calibration date April 2014. Laser output levels were substantially the same to the predicate within the accepted +/-10 tolerance range of the laser specifications.
- HMLC 41 & 82 use identical laser modules as the Predicate Device. A review of the Laser module specifications and Certificate of Compliance confirms wavelength, divergence and power levels to be identical.

The results of the testing demonstrate that the modified devices (HMLC 41 & 82) operated as intended and are as safe and effective as the predicate device.