SEP 2 6 2011

K112524

6. 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
777 Yamato Rd. Suite 105
Boca Raton, FL 33431
(561) 417-0200
research@hairmax.com
Establishment Registration Number: 3006182775

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

Date: August 30, 2011

Proprietary Name: HairMax LaserComb

Common or Usual Name: Lamp, nonheating, for promotion of hair growth.

Product Code: OAP

Classification Name: 21 CFR 890.5500 Infrared lamp

Predicate Device: HairMax Lux 9 K110233

Device Description:

Similar to the HairMax Lux 9 K110233, the modified HairMax Advanced 7 and Pro 12 consist of 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 the laser light reaches the user's scalp.

Intended Use / Indications for Use

The HairMax LaserComb Advanced 7 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.

The HairMax LaserComb Pro 12 is indicated to treat Androgenetic Alopecia and promote hair growth in females with who have Ludwig-Savin Scale I-4, II-1, II-2 or frontal and Fitzpatrick Skin Types I to IV.

Technological Characteristics

The modifications to the HairMax Lux 9 since its previous clearance in K110233 do not alter the safety or efficacy of the device. The predicate device contains 9 laser modules. The modified devices use the exact same laser modules and hair parting teeth mechanism. The difference in the predicate versus modified device is the quantity of the laser modules. The Advanced 7 contains 7 laser modules and the Pro 12 contains 12 laser modules. Adjustments in treatment time compensate for the different number of laser modules.

Nonclinical Testing

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 10. The HairMax Advanced 7 and Pro 12 were subject to the same preclinical requirements as the predicate device. Performance testing was conducted to confirm compliance to design specifications; all functions were verified to operate as designed.

Substantial Equivalence

The Advanced 7 and Pro 12 are as safe and effective as the predicate device, HairMax Lux 9. The subject devices have the same intended use of affecting hair growth as the predicate device. The subject devices have the same indications, *i.e.*, treating androgenetic alopecia, and the same specific indication of promoting hair growth in females, who have Ludwig-Savin Scale I-4, II-1, II-2 or frontal and Fitzpatrick Skin Types I to IV, as the predicate device.

The Advanced 7 and Pro 12 are identical in technological characteristics as the device cleared in K110233, including its laser power, wavelength, laser delivery method, its comb component, its instructions for use and its audible timer. The changes in the number of laser modules does not change the safety or effectiveness.

Conclusion:

The Advanced 7 and Pro 12 have the following similarities to the HairMax Lux 9:

- has the same indicated use,
- same identical laser modules
- same hair parting teeth
- uses the same operating principle
- incorporates the same basic device design and physical properties
- incorporates the same materials

Therefore the modification to the Lux 9 can be found substantially equivalent to the HairMax LaserComb cleared in K110233.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Lexington International, LLC
% Olsson Frank Weeda
Casper E Uldriks, Esq.
1400 16th Street Northwest, Suite 400
Washington, District of Columbia 20036

SEP 26 2011

Re: K112524
Trade/Device Name: HairMax Advanced 7, HairMax Professional 12
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: OAP
Dated: September 16, 2011
Received: September 19, 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,

for

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

Enclosure

5. Indications for Use

510(k) Number (if known): K112524

Device Name: HairMax Advanced 7, HairMax Professional 12

Indications for Use:

The HairMax LaserComb Advanced 7 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.

The HairMax LaserComb Professional 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 _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

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

510(k) Number K112524