K093499

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

6. 510(k) Summary

Lexington International, LLC

NOV 2 3 2009

HairMax LaserComb ver. 5.2

Submitter's Contact Information

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Manufacturer:	Lexington International, LLC

Establishment Registration Number: 3006182775

Official Correspondent

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Trade Name: HairMax LaserComb

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

Product Code: OAP

K093499

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

Classification Name: 21 CFR 890.5500 Infrared lamp

Predicate Device: HairMax LaserComb K060305

November 9, 2009

Device Description:

Similar to the HairMax LaserComb K060305, the modified HairMax LaserComb consists 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.

The predicate unit operates from solely on a class 2, UL and CUL rated wall transformer. The modified unit adds a Lithium ion battery power supply option. In addition, cosmetic changes are being made to the device color and exterior plastic housing. Changes do not alter form fit or function as compared to the predicate device.

Intended Use / Indications for Use

The HairMax LaserComb is indicated to promote hair growth in males, 30-60 years of age with androgenetic alopecia who have Norwood Hamilton Classification IIa – V patterns of hair loss and Fitzpatrick Skin Types I to IV.

Technological Characteristics

The modifications to the HairMax LaserComb since its previous clearance in K060305 include changes to available power supply, and consequently the device casing dimensions and color. These minor differences do not affect the safety or performance of the device and do not change the intended use of the HairMax LaserComb.

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 modified HairMax LaserComb was 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 modified HairMax LaserComb is as safe and effective as the predicate device. The modified device has the same intended use of affecting hair growth as the predicate device. The modified HairMax LaserComb has the same indications, *i.e.*, treating androgenetic alopecia, and the same specific indication of promoting hair growth in males, 30-60 years of age with androgenetic alopecia who have Norwood-Hamilton Classifications of I to V patterns of hair loss and Fitzpatrick Skin types of I-IV as the predicate device.

The modified HairMax LaserComb is identical in technological characteristics as the device cleared in K060305, including its laser power, wavelength, laser delivery method, its comb component, its instructions for use and its audible timer. The cosmetic change to device color and dimensions of the exterior plastic housing and addition of a battery does not affect the HairMax LaserComb's fundamental scientific technology.

Conclusion:

The modified HairMax LaserComb has the following similarities to the HairMax LaserComb:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design and physical properties,
- incorporates the same materials.

Therefore the modification to the modified HairMax LaserComb can be found substantially equivalent to the HairMax LaserComb cleared in K060305.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Lexington International, LLC
% M Squared Associates, Inc.
Ms. Cherita James
Regulatory Consultant
901 King Street, Suite 200
Alexandria, Virginia 22314

NOV 23 2009

Re: K093499
Trade/Device Name: HairMax LaserComb
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP, GEX
Dated: November 10, 2009
Received: November 12, 2009

Dear Ms. James:

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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

5. Indications for Use

510(k) Number (if known): K093499

Device Name: HairMax LaserComb

Indications for Use:

The HairMax LaserComb is indicated to promote hair growth in males, 30-60 years of age with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V patterns of hair loss 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)

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

510(k) Number K093499