K060305

510(k) SUMMARY

Lexington International, LLC LaserComb

Submitter's Contact Information

JAN 18 2007

Name: David Michaels, Managing Director

Address: Lexington International, LLC
2650 North Military Trail, Suite 360
Boca Raton, FL 33431

Telephone: (561) 417-0200
Facsimile: (561) 892-0747

Name of Device and Name/Address of Sponsor

Trade Name: HairMax LaserComb

Sponsor Contact Information: David Michaels
Lexington International, LLC
2650 North Military Trail, Suite 360
Boca Raton, FL 33431

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

Classification Name: Infrared lamp per 21 CFR 890.5500

Predicate Devices

Device Trade Name	Manufacturer
Robi Combi	Epilady 2000, LLC
DermaLight Psoracomb	Solitec GMBH
Quantum WARP 10 Light Delivery System	Quantum Devices, Inc.
Lumiphase-R	Opusmed Inc.
TerraQuant MQ2000 Laser Therapy Device	Escada International, Inc.
MLT R694 Ruby Laser System	Medical Laser Technologies Ltd.
L600 Hair Removal	A&M Technology
Violet Ray Device	Manufacturer unknown
Vacuum Cap	Evans
Raydo and Wonder Brush	Dr. Scott

Date Prepared: September 27, 2006

K060305

Intended Use / Indications for Use

The LaserComb is indicated to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV.

Technological Characteristics

The LaserComb consists of a hand-held low level laser device that promotes 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. When in use, the device emits a beep every four seconds to notify the user to move the device to a new section of the scalp.

Performance Data

A multicenter, randomized, placebo-controlled trial was conducted at four sites in the United States. Subjects received either the LaserComb or a sham device. Subjects were instructed to use the device three times per week on nonconcurring days for a total of 26 weeks. Subjects in the LaserComb treatment group had significantly greater increases in mean terminal hair density than subjects in the placebo group. Subjects in the LaserComb group also had significantly better subjective assessments of overall hair regrowth than subjects in the placebo group. No subject experienced a serious adverse event and the adverse event profiles were similar between the two treatment groups. In all instances, the LaserComb functioned as intended and the hair regrowth observed was as expected.

Substantial Equivalence

The LaserComb is as safe and effective as a combination of those predicate devices. The LaserComb has the same intended use of affecting hair growth as its preamendments hair growth predicate devices and its laser hair removal predicates. In addition, the LaserComb has the same general indications, *i.e.*, treating baldness, and the same specific indication of promoting hair growth as its preamendments predicate devices. The LaserComb also has many of the same or similar technological characteristics as a combination of its predicate devices, including its red laser wavelength, its split beam laser delivery system, its comb component, and its audible timer. The technological differences between the LaserComb and its predicate devices, namely use of red laser to promote hair growth, do not raise new questions of safety or effectiveness for several reasons. First, the safety and effectiveness profile of that type of laser is well-established. Second, FDA's clearance of a red laser with virtually the same wavelength (for a cosmetic-type indication) confirms the favorable risk benefit ratio of red lasers, even when they are used for cosmetic-like indications. Finally, the clinical data summarized in the 510(k) notice confirms the safety and effectiveness of the LaserComb for OTC use in promoting hair growth in its intended patient population, despite those technological characteristics. For those reasons, the LaserComb satisfies FDA's substantial equivalence with respect to both the intended use and technological characteristics.

K060305

There are some technological differences between the LaserComb and its predicate devices. Namely, none of the predicate devices deliver laser light to the scalp to promote hair growth. For this reason, Lexington conducted a clinical study of the LaserComb to show that the device functions as intended for its proposed indication without serious side effects.

The clinical data demonstrates that the LaserComb is effective in promoting hair growth and does not present any safety issues. Therefore, the LaserComb satisfies FDA's substantial equivalence criteria. Thus, FDA should clear the device via the 510(k) notice containing clinical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lexington International, LLC
% King & Spaulding, LLP
Mr. Edward M. Basile
Senior Partner
1700 Pennsylvania Avenue, Northwest
Washington, District of Columbia 20006-4706

JAN 16 2007

Re: K060305
Trade/Device Name: HairMax LaserComb
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Hair Growth
Regulatory Class: II
Product Code: OAP
Dated: September 29, 2006
Received: September 29, 2006

Dear Mr. Basile:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K060305

Device Name: HairMax LaserComb

Indications for Use:

The LaserComb is indicated to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V 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 General, Restorative and Neurological Devices

510(k) Number K06 0305