

K060305

**510(k) SUMMARY**

**Lexington International, LLC LaserComb**

**Submitter's Contact Information**

Name: David Michaels, Managing Director

JAN 18 2007

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**

Robi Combi  
DermaLight Psoracomb  
Quantum WARP 10 Light Delivery System  
Lumiphase-R  
TerraQuant MQ2000 Laser Therapy Device  
MLT R694 Ruby Laser System  
L600 Hair Removal  
Violet Ray Device  
Vacuum Cap  
Raydo and Wonder Brush

**Manufacturer**

Epilady 2000, LLC  
Solitec GMBH  
Quantum Devices, Inc.  
Opusmed Inc.  
Escada International, Inc.  
Medical Laser Technologies Ltd.  
A&M Technology  
Manufacturer unknown  
Evans  
Dr. Scott

**Date Prepared:** September 27, 2006

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## **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.

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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.



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 18 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.

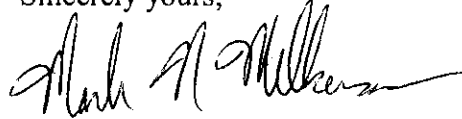
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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)

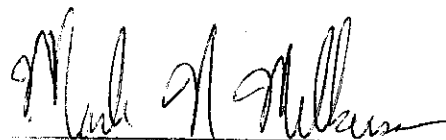
AND/OR

Over-The-Counter Use X \_\_\_\_\_  
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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