

HairMax LaserComb

510K Summary

(September 27, 2006)

and

FDA Clearance to Market Letter

(January 18, 2007)



Documents

510(k) SUMMARY

Lexington International, LLC LaserComb

Submitter's Contact Information

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JAN 18 2007

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Name of Device and Name/Address of Sponsor

Trade Name: HairMax LaserComb

Sponsor Contact Information: David Michaels
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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

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.

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.