

## HairMax LaserComb<sup>®</sup> Clinical Studies

Seven clinical studies have been conducted on the HairMax LaserComb with a total of 460 subjects. Six of these studies were double-blinded, control-device trials conducted at top major research centers such as the Cleveland Clinic, University of Miami and University of Minnesota.

### STUDY DESIGN AND METHODS

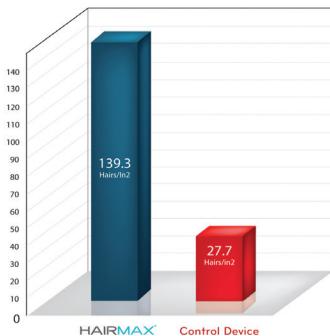
Clinical study participants were divided into two groups. One group used the HairMax LaserComb and the other group used a control device that looked like the LaserComb but did not provide any laser light. All of the LaserComb clinical studies complied with the strict regulations of FDA Good Clinical Practices.

During these 6 month studies, subjects treated their hair once per day, 3 times a week, on non-consecutive days. The number of thick, normal, healthy hairs in the target area were counted at the beginning of the studies and then again at 16 weeks and 26 weeks.

### CLINICAL TRIAL PROVES EFFICACY IN MALES AND FEMALES

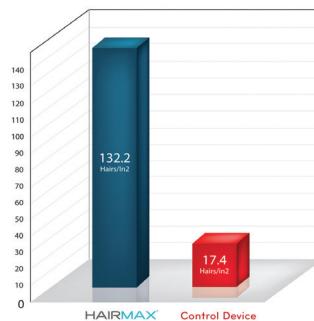
Over 90% of participants experienced significant hair growth with a combined average increase in hair count of 149 additional hairs per sq. inch. Additionally, LaserComb users report increased density, reversal of the thinning process, increased fullness of hair and an overall improvement of scalp health. There have never been any reports of serious side effects occurring.

Mean Terminal Hair Count Changes From Baseline in MALES  
26 Weeks



**Males:** The results of these studies in males showed that the average number of terminal hairs per square inch increased by 139.3 hairs at the completion of the study (26 weeks) vs. 27.7 hairs for the control device.

Mean Terminal Hair Count Changes From Baseline in FEMALES  
26 Weeks



**Females:** In the female study the average number of terminal hairs increased by 132.2 hairs per square inch at the completion of the study (26 weeks) vs. 17.4 hairs for the control device.

# HairMax LaserComb® FDA Clearance for Males and Females: A Milestone in Treating Hair Loss and the Promotion of Hair Growth\*

Since 2007, there are a total of 6 FDA Clearances of the HairMax LaserComb. When a company receives this clearance, there are stringent rules and high standards put into place covering all aspects of manufacturing and quality control. The HairMax LaserComb is the first and only home use Laser PhotoTherapy home use device that has been reviewed by the FDA and cleared for the treatment of androgenetic alopecia (pattern hair loss) in both males and females.\*

## FDA INDICATION FOR USE

All models of the LaserComb have undergone extensive clinical studies on both men and women and have been granted FDA 510(k) Clearance with the following indications:

\*The HairMax LaserComb is indicated to treat Androgenetic Alopecia, and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and who both have Fitzpatrick Skin Types I to IV.

## WHAT DOES FDA 510(k) CLEARANCE MEAN?

The FDA 510(K) Clearance is a rigorous process conducted by the FDA to ensure the safety and effectiveness of a device. Before you can legally sell a medical device in the U.S., the FDA must validate its safety and review evidence of effectiveness.

The HairMax LaserComb was required to undergo demanding clinical studies to prove conclusively that it was effective and safe in promoting hair growth and treating pattern hair loss. Other tests for laser and electrical safety must also be submitted to the FDA for review before Clearance will be granted.

In addition to the clinical studies, the FDA requires the device to be manufactured in a quality controlled facility adhering to the strict standards of FDA's Good Manufacturing Practices (GMP). The FDA conducts periodic audits of the manufacturing facility to ensure the product is being built to the highest quality standards possible.

Lexington is committed to providing a product that meets these standards and is focused on your complete satisfaction and confidence in its quality for your complete satisfaction.