

FDA Approval – Promoting Hair Growth with Lasers

Intended Use

Lasers have now been proven 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.

In the study, subjects who had been frequently exposed to laser light had shown a significant increase in their hair density over a 26 week period then those who were not exposed to the laser. Subjects had also shown a greater number of re-grown hairs than the subject in the placebo group. No one suffered any side effects.

Evidence

Lasers have the same intended use of affecting hair growth as its pre-amendments hair growth predicate devices and its laser hair removal predicates. In addition, laser have the same general indications, *i.e.*, treating baldness, and the same specific indication of promoting hair growth as its pre-amendments predicate devices. Lasers also have 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, and its audible timer. First, the safety and effectiveness profile of red wavelength lasers are 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 5 10(k) notice confirms the safety and effectiveness of lasers for use in promoting hair growth in its intended patient population, despite those technological characteristics. For those reasons, Lasers satisfy the FDA's substantial equivalence with respect to both the intended use and technological characteristics.

Lasers have satisfied the FDA's criteria for promoting hair growth.