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510(k) Summary

Apira Science, Inc.

DEC 0 5 2012

Submitter's Contact Information

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Name of Device and Name/Address of Sponsor

Trade Name:	igrow-II Hair Growth System
Sponsor Contact Information:	Morgan Pepitone Apira Science, Inc. 2601 Main Street, Suite 530 Irvine, CA 92614

Common or Usual Name: Lamp, non-heating, for promotion of hair growth

Classification Name: Infrared lamp per 21 CFR 890.5500

Classification Code: OAP (Laser, comb, hair)

Predicate Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International, LLC

Reference Devices:

MEP-90	Midwest RF

Date Prepared: July 20, 2012
November 13, 2012 Revised

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Intended Use / Indications for Use

The igrow-II Hair Growth System is indicated to promote hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Phototypes I to IV.

Technological Characteristics

The Igrow-II Hair Growth System consists of 21 red visible light, diode lasers and 30 red light super-luminescent diodes configured within an outer helmet and protective inner liner. The use of diode lasers and non-laser LEDs provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.

Performance Data:

A multi-center, randomized, double blinded, placebo controlled, prospective trial was conducted at two sites in the United States. Subjects received either the igrow-II Hair Growth System, unlabeled with any markings or an equivalent, red light, incandescent light system. Identical, helmet housings were used for both light sources to further mask the actual test device from the placebo device. Adequate data, from prior testing, was already available to the sponsor, validating the efficacy of the igrow-II Hair Growth System , obviating the need to test lasers versus LEDs, which the sponsor and the FDA consider equal in their tissue interaction profile. All subjects self-administered treatments, at home, for 16 weeks, with either the actual test device or the placebo device. Treatments were administered every other day, for 20 minutes. Subjects treated in the actual test laser group demonstrated a 100 % effectiveness; that is, all of the subjects showed a positive result for an increase in terminal hair counts. In the placebo group, there was some incremental improvement over baseline and some demonstrated a decrease over baseline. Overall, the active group demonstrated a 39% positive variance over the placebo group from baseline. Most significant was the actual test group's decrease in terminal hair counts which was zero compared to the placebo group which was highly significant. This points strongly to the hypothesis that red laser and LED light's characteristics for delivering precise,

controlled, consistent irradiance is essential in effecting a reproducible therapeutic outcome . There were no anticipated adverse events and none were reported from either therapy administered that were study related. In all instances the igrow-II Hair Growth System functioned as anticipated and hair re-growth was observed to be significantly greater than that of the incandescent placebo system.

Substantial Equivalence

The igrow -II Hair Growth System is as safe and effective as the other device in its class, the Hairmax Lasercomb. This is a unique distinction for the sponsor of the igrow-II Hair Growth System because the Food and Drug Administration has created a new classification for this device, effective January 18, 2007. It is called OAP. There are no other devices listed within this classification, which the sponsor believes serves to narrow down the predicate device issue to one key comparison. Does the igrow-II Hair Growth System demonstrate substantial equivalence to the Hairmax Lasercomb for the indicated use and to the MEP for the specific design characteristic? The sponsor believes that with the exception of the configuration of the predicate device, the Hairmax Lasercomb, which is a hair comb configuration and the igrow-II Hair Growth System , is a helmet, the devices are identical in the key areas that effect safety and efficacy. The MEP -90 is offered as a reference proof of the functionality and acceptability of a helmet design, both technically and clinically.

Both systems, which use red light diode lasers and/or the equivalent, super-luminescent, light emitting diodes are classified as class IIIa/3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same. The sponsor believes that the difference in the physical appearance or in the method of delivering the radiant energy of the two systems is of no consequence and does not effect the therapeutic value or the safety profile. The sponsor believes that difference between a hand-held laser system (the Hairmax Lasercomb) and one that is a hands-free helmet design (the igrow-II Hair Growth System) does not create a performance difference, but rather a physical appearance difference only. This design difference is mitigated by the marketing clearance issued to the MEP90, which is also a helmet design , demonstrating that a hair comb style device is not a performance requirement for efficacy. Finally, the clinical data summarized in the 510(k) notice confirms the safety and efficacy of the igrow-II Hair Growth System for OTC Use, according to Part 21 CFR 801 Subpart C). For these reasons, the igrow-II Hair Growth System satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

With the relatively new classification of OAP, the sponsor respectfully proposes that the FDA has acknowledged that Low-Level Laser/Light Therapy is a viable modality for treating androgenetic alopecia in the specified patient group and that the red light lasers in class IIIa/3R, used in the igrow-II Hair Growth System, are substantially equivalent to the Hairmax Lasercomb .

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The clinical data presented by the sponsor for the igrow-II Hair Growth System further validates that red light lasers are effective in promoting hair growth and does not present any safety issues. Therefore, the igrow-II Hair Growth System satisfied the FDA's substantial equivalence criteria. Thus, the 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

IGrow II Hair Growth System
% NST Consulting, LLC
Mr. Raymond R. Blanche
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

December 5, 2012

Re: K122248
Trade/Device Name: igrow-II Hair Growth System
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Hair Growth
Regulatory Class: Class II
Product Code: OAP
Dated: November 16, 2012
Received: December 03, 2012

Dear Mr. Blanche:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K 122248

Device Name: igrow-II Hair Growth System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED)

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use __X__ (Part 21 CFR 801 Subpart D)

OR

Over-the -Counter Use _____ (Part 21 CFR 801 Subpart C)

Neil R Ogden
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(Division Sign-off) for MXM
Division of Surgical Devices
510(k) Number___K122248____