



Food and Drug Administration  
10903 New Hampshire Avenue  
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August 21, 2014

Apira Science, Inc.  
% NST Consulting, LLC  
Raymond R. Blanche  
641 Shunpike Road, Suite 311  
Chatham, New Jersey 07928

Re: K141567  
Trade/Device Name: igrow-II Hair Growth System  
Regulation Number: 21 CFR 890.5500  
Regulatory Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: OAP  
Dated: July 25, 2014  
Received: July 31, 2014

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Indications for Use**

510(k) Number (if known)

K141567

Device Name

igrow-II Hair Growth System

Indications for Use (Describe)

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

K141567

510(k) Summary

Apira Science, Inc.

**Submitter's Contact Information**

Name: Raymond R. Blanche  
Address NST Consulting, LLC  
641 Shunpike Road, Suite 311  
Chatham, NJ 07928  
Telephone: (973-539-7444  
Facsimile: (973) 539-7445

**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

**Date Prepared:** February 10, 2014

**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 Classification 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:**

The data presented in this submission is restricted to Self-Selection and Usability to include comprehension of user instructions and warnings and precautions. The results of a Pre-submission meeting provided the objectives that must be fulfilled for the igrow to be classified as an Over-the-Counter device. This guidance stipulated that a minimum of an 80% success rate must be achieved for the Intended Use of OTC to be granted. The testing was administered to 30 male subjects of any age, educational background, race, disease status present or pre-education about the testing to be performed. This was designed to provide for the broadest test criteria without any bias being imposed, thereby assessing the real world capability of the average male, "retail customer" who might wish to purchase a device without the benefit of a physician or other qualified health care provider to provide counsel as is the case with prescription devices.

The igrow testing demonstrated a pass rate of 83.33%, satisfying the FDA's requirements for an Over-the-Counter Intended Use.

**Substantial Equivalence:**

The requirements set for substantial equivalence in the traditional sense, do not have applicability in this process because the threshold for success has been set by the formal guidance provided to the sponsor by through the FDA's Presubmission Meeting process. However, The Hairmax Lasercomb has been cleared with the Intended Use of Over-the-Counter and therefore, the igrow Hair Growth System is substantially equivalent to the Hairmax Lasercomb by meeting or exceeding the minimum requirements set by the FDA's process of Presubmission Meeting guidance.