Records processed under FOIA Request # 2013-9808 Released by CDRH on 09-29-2015

K122248

510(k) Summary

Apira Science, Inc.

DEC 05 2012

Submitter's Contact Information

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

Reference Devices:

MEP-90	Midwest RF

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K122248/ 2/4

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,

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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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K122249 4/4

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.

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INDICATIONS FOR USE

510(k) Number: K 122248

Device Name: igrow-II Hair Growth System

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 of Skin Phototypes I to IV.

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

_____ _____ _____ _____

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use __X__ OR Over-the -Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Neil R Ogden
2012.12.03 14:33:36 -05'00'

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K122248 V1

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
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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

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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

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(K 121580)

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
Peter D. Rumm -S					
2012.12.05 11:07:46 -05'00'					

f/t: RPW/tdm:9/20/12

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms

f/t:RPF:kdm:12/5/12

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INDICATIONS FOR USE

510(k) Number: K 122248

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Neil R Ogden
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Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

* * * COMMUNICATION RESULT REPORT (DEC. 6. 2012 1:33PM) * * *

FAX HEADER 1:
FAX HEADER 2:

NSMITTED/STORED : DEC. 6. 2012 1:26PM

LE MODE	OPTION	ADDRESS	RESULT	PAGE
1620 MEMORY TX		973 539 7445	OK	4/4

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

IGrow II Hair Growth System
% NST Consulting, LLC
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December 5, 2012

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Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Hair Growth
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Product Code: OAP
Dated: November 16, 2012
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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K122248/S2_____

Date: December 3, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Apira Science, Inc.
Device Name: igrow Hair Rejuvenation System II
Contact: Raymond R. Blanche
Phone: 973-539-7444
Fax: 973-539-7445
Email: NSTConsultingLLC@gmail.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the igrow Hair Rejuvenation System II into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

The igrow hair growth system is a helmet type device that incorporates 21 red diode lasers and 30 red super-luminescent LED's. The helmet and light exposure system covers 1/3 of the head which corresponds to the hair growth area. The helmet has ear flaps which help correctly orient the helmet in terms of correct placement on the head and these ear flaps also contain speakers through which music can be played during the treatment session.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?			
Is the device sterile?		X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

IV. Indications for Use

It is indicated to promote hair growth in males with androgenic alopecia who have Norwood Hamilton Classification of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV.

V. Predicate Device Comparison

The company has identified two predicates, the HairMax, cleared under K06035 for the same indication for use and the MEP-90 as a technical predicate since it is a bonnet type device cleared under K091496. The igrow is not truly equivalent to either of these in terms of technology but will be eligible for a determination of Substantial Equivalence based on clinical trial data if the data does demonstrate successful hair growth compared to a sham control group and the clinical study design is deemed acceptable.

VI. Labeling

The company has provided a User Manual for the requested indication for use. Since the company had originally requested over-the-counter clearance the user manual was written for over-the-counter users. Review of the manual has identified a number of issues that are related to the over-the-counter sale as well as other issues related to claims for rejuvenation, stronger and thicker hair.

In Supplement 1 the company provided a totally revised User Manual. This manual has deleted all references to hair rejuvenation and other language that would represent an over-the-counter device. The manual does clearly state that treatment is for 25 minutes and is to be performed only once a day and that treatment should only be performed every other day. The manual has clear directions regarding assembly of the device, operation of device in terms of correctly placing power cords, illustrations of the control system and what information the user will see at the different stages of operation, and directions for cleaning.

VII. Sterilization/Shelf Life/Reuse

The device is not sold sterile. Shelf life is not an issue. The company has provided information on cleaning between uses with comments related to hair oils and lotions.

VIII. Biocompatibility

The company has provided information on material used in the device. The inner lining does not come into contact with the scalp.

IX. Software

The issue of software use was raised during the initial review since there is a mention of a microprocessor in the device description. In Supplement 1 the company responded to our concern related to apparent use of a microprocessor by clearly stating that the device is an analogue system and does not use any software either written by the company or obtain as off-the-shelf software. The company has clarified the information in the submittal related to their manufacturer's Discrete Control Logic and Failsafe Monitors again stating that these are analogue only and that no software is used in these circuitry control systems.

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The company has provided Standards form 3654 and has stated that the device meets classification of laser equipment in accordance with IEC 60825-1 Edition 1.2, 2001-08 and IEC 60601-2-22. The company has stated conformance and testing according to IEC 60601-1 and 60601-1-2.

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

The clinical study was reviewed by Betsy Ballard, MD for clinical issues and by Jianxiong Chu for statistical issues. Issues identified by these consulting reviewers were conveyed to the company with initial responses to their issues provided in Supplement 1 with follow-up issues responded in Supplement 2. At this time both consultants have recommended that this application be granted a determination of Substantial Equivalence.

The company has provided clinical data to support their application. (b)(4) [redacted] (b)(4).

In Supplement 1 the company clarified the history of the protocols used in the study related to the dates on the protocol copies included in this application. (b)(4) [redacted] (b)

(b)(4) [redacted].

In this Supplement the company has provided the following responses to statistical and clinical issues identified in our review of Supplement 1.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

In addition to the above responses the company has also provided a revised stand alone indication for use page and a revised 510(k) Summary (b)(4) .

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

(b)(4)

4. There are no new types of safety issues. Both devices use light based technology.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5. There are recognized methods to determine effectiveness, that (b)(4) (b)(4)

6. The company did provide (b)(4).

XV. Deficiencies

XVI. Contact History

(b) (6) was requested to submit the responses to our issues identified in our review of Supplement 1 by electronic mail before submitting the official copy. Based on our review of this information (b) (6) was contacted by electronic mail on (b)(4) and notified that he could now submit the official copies of this information.

XVII. Recommendation SE

Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Hair Growth
Regulatory Class: Class II
Product Code: OAP

Richard P. Felten
2012.12.05 11:14:12 -05'00'

Reviewer Date

Neil R Ogden
2012.12.05 11:18:24 -05'00'

Branch Chief Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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December 3, 2012

Review of K122248/S2

Submitted By Apria Sciences, Inc.

Reviewed by Richard P. Felten, DSD, GSDB1

Peter D. Rumm -S
2012.12.05 11:10:04 -05'00'

Richard P. Felten
2012.12.03 14:59:15 -05'00'

This Supplement is the company's response to our request for additional information related to clinical and statistical issues raised by our consulting reviewers. The additional issues were sent to Mr. Blanche by electronic mail on November 13, 2012 with a request to provide the response by return mail prior to submitting the official document. The responses were received by electronic mail on November 16, 2012 and forwarded to the consultants for their review. Both the statistical and clinical consultant accepted the responses as adequate and indicated that they had no additional questions. The clinical consult was performed by Betsy Ballard, MD and the statistical consult was performed by Jianxiong Chu, Ph.D.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Neil R Ogden
2012.12.05 11:21:15
-05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

*****NOTE: This form is OPTIONAL for holds, and REQUIRED for final decisions*****

From: Reviewer Name Richard P. Felten

Subject: 510(k) Number K122248/S2

To: The Record

Please list CTS decision code SE_____

o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

o Hold (Additional Information or Telephone Hold).

X Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- o NO NSE for lack of predicate
- o NI NSE for new intended use
- o NQ NSE for new technology that raises new questions of safety and effectiveness
- o NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- o NP NSE for lack of performance data
- o NS NSE no response
- o NL NSE for lack of performance data AND no response
- o NM NSE pre-amendment device call for PMAs (515i)
- o NC NSE post-amendment device requires PMAs
- o NH NSE for new molecular entity requires PMA
- o TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM		X	

Rev. 9/20/12 – added digital concurrence table

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number **Class*** **Product Code**

21 CFR 890.5500_____Class II_____OAP_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Richard P. Felten 2012.12.03 08:14:11 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2012.12.03 14:35:12 -05'00'
Division Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name _____

Subject: 510(k) Number K122248 / S2

To: The Record

Please list CTS decision code _____

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
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☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States based clinical studies only: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If study was			

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief) (Branch Code) (Date)

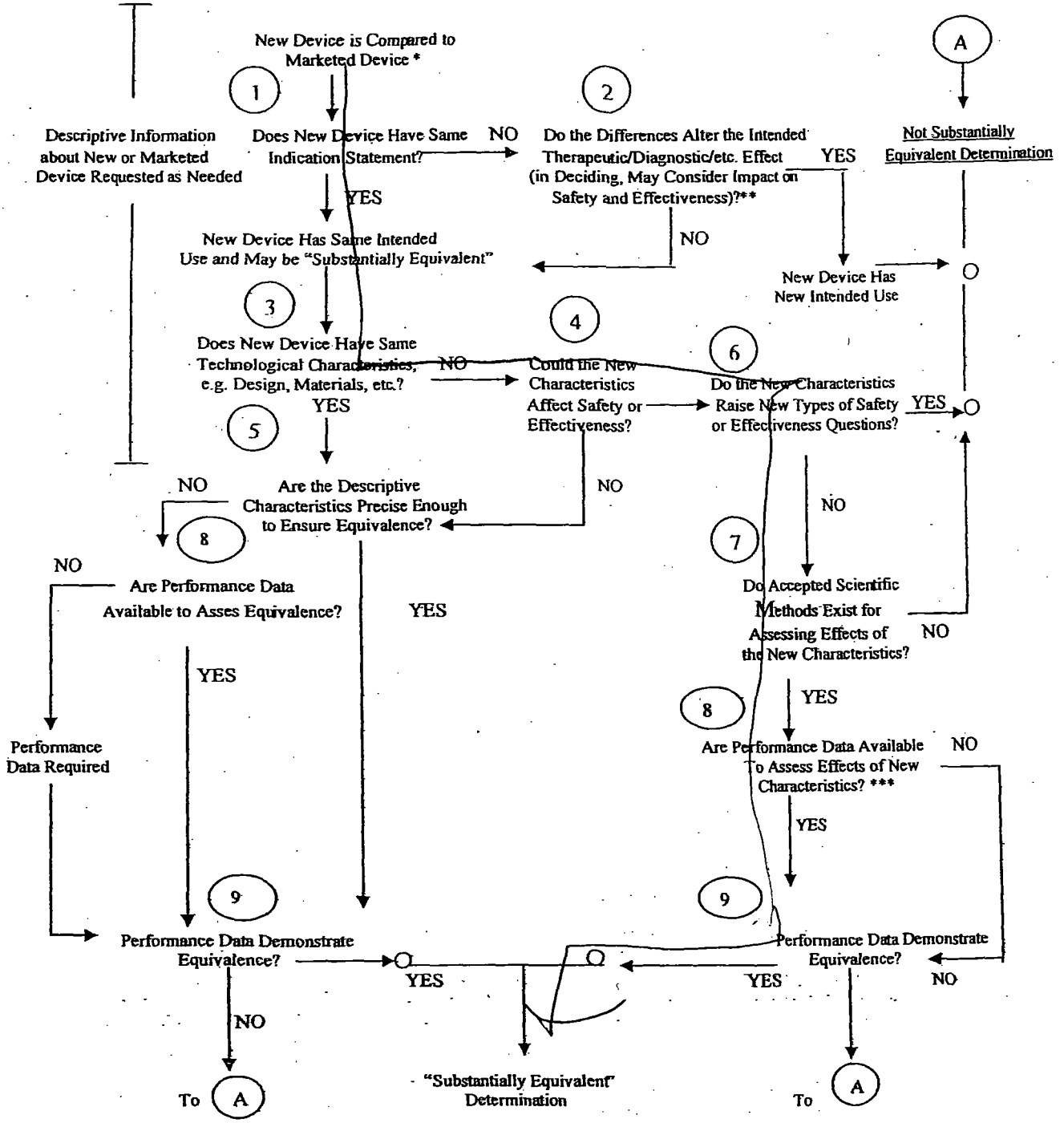
Final Review:

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K122248/S2_____

Date: December 3, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Apira Science, Inc.
Device Name: igrow Hair Rejuvenation System II
Contact: Raymond R. Blanche
Phone: 973-539-7444
Fax: 973-539-7445
Email: NSTConsultingLLC@gmail.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the igrow Hair Rejuvenation System II into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

The igrow hair growth system is a helmet type device that incorporates 21 red diode lasers and 30 red super-luminescent LED's. The helmet and light exposure system covers 1/3 of the head which corresponds to the hair growth area. The helmet has ear flaps which help correctly orient the helmet in terms of correct placement on the head and these ear flaps also contain speakers through which music can be played during the treatment session.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?			
Is the device sterile?		X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

IV. Indications for Use

It is indicated to promote hair growth in males with androgenic alopecia who have Norwood Hamilton Classification of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV.

V. Predicate Device Comparison

(b)(4) [redacted]
(b)(4)

VI. Labeling

The company has provided a User Manual for the requested indication for use.(b)(4) [redacted]
(b)(4)

In Supplement 1 the company provided a totally revised User Manual. (b)(4) [redacted] he
(b)(4) [redacted]
(b)(4) [redacted] The manual has clear directions regarding assembly of the device, operation of device in terms of correctly placing power cords, illustrations of the control system and what information the user will see at the different stages of operation, and directions for cleaning.

VII. Sterilization/Shelf Life/Reuse

The device is not sold sterile. Shelf life is not an issue. The company has provided information on cleaning between uses with comments related to hair oils and lotions.

VIII. Biocompatibility

The company has provided information on material used in the device. The inner lining does not come into contact with the scalp.

IX. Software

(b)(4) [redacted]

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The company has provided Standards form 3654 and has stated that the device meets classification of laser equipment in accordance with IEC 60825-1 Edition 1.2, 2001-08 and IEC 60601-2-22. The company has stated conformance and testing according to IEC 60601-1 and 60601-1-2.

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

The company has provided clinical data to support their application. (b)(4) [redacted] (b)(4) .

(b)(4) [redacted] (b) .

(b)(4) [redacted] .

In this Supplement the company has provided the following responses to statistical and clinical issues identified in our review of Supplement 1.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

In addition to the above responses the company has also provided a revised stand alone indication for use page and a revised 510(k) Summary (b)(4) .

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

(b)(4)

4. There are no new types of safety issues. Both devices use light based technology.

5. There are recognized methods to determine effectiveness, that is, (b)(4) (b)(4) .

6. The company did provide (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

XV. Deficiencies

XVI. Contact History

(b)(4)

XVII. Recommendation SE
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP

Richard P. Felten
2012.12.03 07:10:16 -05'00'

Reviewer | Date

Neil R Ogden
2012.12.03 14:26:57 -05'00'

Branch Chief | Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

December 3, 2012

Review of K122248/S2

Submitted By Apria Sciences, Inc.

Reviewed by Richard P. Felten, DSD, GSDB1

Richard P. Felten
2012.12.03 14:59:15 -05'00'

This Supplement is the company's response to our request for additional information related to clinical and statistical issues raised by our consulting reviewers. The additional issues were sent to Mr. Blanche by electronic mail on November 13, 2012 with a request to provide the response by return mail prior to submitting the official document. The responses were received by electronic mail on November 16, 2012 and forwarded to the consultants for their review. Both the statistical and clinical consultant accepted the responses as adequate and indicated that they had no additional questions. The clinical consult was performed by Betsy Ballard, MD and the statistical consult was performed by Jianxiong Chu, Ph.D.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Consult Review
K122248

Date: 11-28-20 **Office:** ODE

From: Betsy Ballard, MD FACS **Division:** DOS/GSDB1

Device Name: iGrow II Hair Growth System
Apira Science, Inc.

Introduction:

I have been asked by Mr Richard Felten, Lead Reviewer, to provide a clinical consult review for the data provided in this 510(k) submission to support a premarket notification. This is a review of their responses to a deficiency letter dated 11/09/2012.

Device Description:
The device is a low-level laser/light system operating at 655 +/-10 nanometers. The physical configuration is that of a helmet containing an inner and outer liner, stabilized with ear phones that are fully functional for listening t musica. The system operates on line voltage at 120 or 240 volts. The helmet's inner liner permits full adjustment to any head shape by means of r 4 adjustable feet with positioning boots. The helmet contains 21, 5-milliwatt-diode lasers and 30, 5mm, through-the-hope super luminescent diodes that emit red light. The system delivers fixed laser emission levels, measured to be 68L/cm^2 for a 20 minute treatment session, which cannot be altered by the operator. The only setting the operator can make is duration of therapy.

The device helmet is constructed of and ABS type plastic. The igrow Hair Rejuvenation System II is a hands free system, requiring no active processes by the user. Only the laser and the LED light contacts the human scalp, emitted directly from the inner liner, without any focusing lens system. The device helmet covers the upper one-third of the head, with orientation from the bridge of the nose in the anterior, towards the occipital notch in the posterior and from the upper most portion of the ear on both sides. The helmet remains approximately 2-4 cm away from the scalp.

Indications for Use:
This has been changed to:

> *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 of Skin Phototypes.*

Reviewer's comments: (b)(4) [redacted]

Review:
I have reviewed the following sections provided by the Sponsor:

- Responses to FDA deficiency letter

My comments are a follows:

(b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

RECOMMENDATION: I see no further issues. Approval.

Betsy Ballard
2012.11.28 18:05:20 -05'00'

Betsy Ballard, MD FACS
General and Surgical Devices Branch
Division of Surgical, Orthopedic and Restorative Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Felten, Richard P.

From: Chu, Jianxiong
Sent: Tuesday, December 04, 2012 10:13 AM
To: Felten, Richard P.
Cc: DBS Reviews
Subject: RE: iGrow K122248
Attachments: K122248 A001 -Igrow hair rejuvenation Sponsor response.docx

Hi, Richard,

Please see the attached as my review (with digital signature).

(b) (4)

Thanks,

Jianxiong (George) Chu
WO Bldg 66 (CDRH) Room 2210
Tel: 301-796-6007
Fax: 301-847-8123
Email: jianxiong.chu@fda.hhs.gov

From: Felten, Richard P.
Sent: Tuesday, December 04, 2012 9:23 AM
To: Chu, Jianxiong
Subject: iGrow K122248

George:

I still need a sign review from you for this document. It is due out today so if you could simply send an e-mail with an attached statement that you have not additional questions and digitally sign it that should be adequate.

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical Devices
General Surgery Devices Branch 1

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

Date: Nov. 21, 2012

From: Mathematical Statistician: Jianxiong Chu
Division of Biostatistics, OSB

Subject: K122238 A001: The igrow Hair Rejuvenation System II for hair loss in males
Apira Science, Inc.

To: Richard P. Felten
ODE/DSORD/GSDB

I. Introduction

The igrow Hair Rejuvenation System II is a Low-Level Laser and Light Therapy device operating at the 655-nanometer wavelength of visible light. Exposure to the laser/light radiation will not cause the human body temperature to sustain any rise in temperature above the base normal of 37.0 degrees centigrade. The system contains an analog system, optical power output monitor that controls laser emission levels (not to exceed 5 ± 20% milliwatts), and is configured as a low-profile helmet, with functional ear phones that are used for music listening and stabilization on the head. Within the helmet are contained 21, 5-milliwatt diode lasers and 30 super luminescent diodes, affixed in an evenly distributed pattern across the inner helmet liner. The laser/light emission level is fixed at approximately 68j/cm^2 and cannot be adjusted by the user/operator. The duration of therapy is the only variable that is operator controlled. The standard therapy session is 20 or 25 minutes, depending on program selection.

(b)(4) [redacted].

In this statistical review, I will address the sponsor's responses to (b)(4) [redacted] (b)(4) [redacted] as conveyed to the sponsor.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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II. Comments

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Reviewer's Comment: Adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

If you have any questions concerning this review please contact me.

Jianxiong Chu

Jainxiong (George) Chu, Ph.D.

Cc:

Phyllis Silverman, M.S.
Medical Device File
Board File

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 03, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248

Product: IGROW II HAIR GROWTH SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

* * * COMMUNICATION RESULT REPORT (DEC. 3. 2012 4:02PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TR SMITTED/STORED : DEC. 3. 2012 4:00PM

F	MODE	OPTION	ADDRESS	RESULT	PAGE
1507	MEMORY TX		973 539 7445	OK	1/1

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 03, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248

Product: IGROW II HAIR GROWTH SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or If any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09/28/2015

K122248/8/S2

nst
CONSULTING, LLC

K04

November 16, 2012

Mr. Richard P. Felten
Center for Devices and Radiological Health
Document Mail Center, W066-0609
10903 New Hampshire Avenue
Silver Spring , MD 20993-0002

FDA CDRH DMC
DEC 03 2012
Received

RE: K122248 Deficiency Letter dated November 9, 2012

Dear Mr. Felten:

Thank you for the opportunity to respond to the questions you have identified in your review of the above referenced premarket notification.

(b) (4)

[redacted]

641 Shunpike Road #311 Chatham, NJ 07928 Tel: 973.539.7441 Fax: 973.539.7445 Email: NSTConsultingLLC@gmail.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

On behalf of the manufacturer, I remain ready to respond to further questions and provide additional documentation in support of answers to questions.

Sincerely,

Raymond R. Blanche
Clinical & Regulatory Affairs Advisor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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: Facsimile:	(973-539-7444 (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

Reference Devices:

MEP-90	Midwest RF

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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 .

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

INDICATIONS FOR USE

510(k) Number: K 122248

Device Name: igrow-II Hair Growth System

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 of Skin Phototypes I to IV.

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

_____ _____ _____ _____

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use __X__ OR Over-the -Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jones, Ashlee *

From: Microsoft Outlook
To: 'nstconsultingllc@gmail.com'
Sent: Tuesday, November 13, 2012 3:37 PM
Subject: Relayed: K122248 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'nstconsultingllc@gmail.com' (nstconsultingllc@gmail.com)
<mailto:nstconsultingllc@gmail.com>

Subject: K122248 Hold Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 13, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248
Product: IGROW HAIR REJUVENATION SYSTEM
On Hold As of 11/13/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808 ; Released by CDRH on 09-29-2015

For further information regarding how various user and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Richard Y. Fa Chen

Subject: 510(k) Number K122248/S001

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		N/A
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
890.5500	II	OAP

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

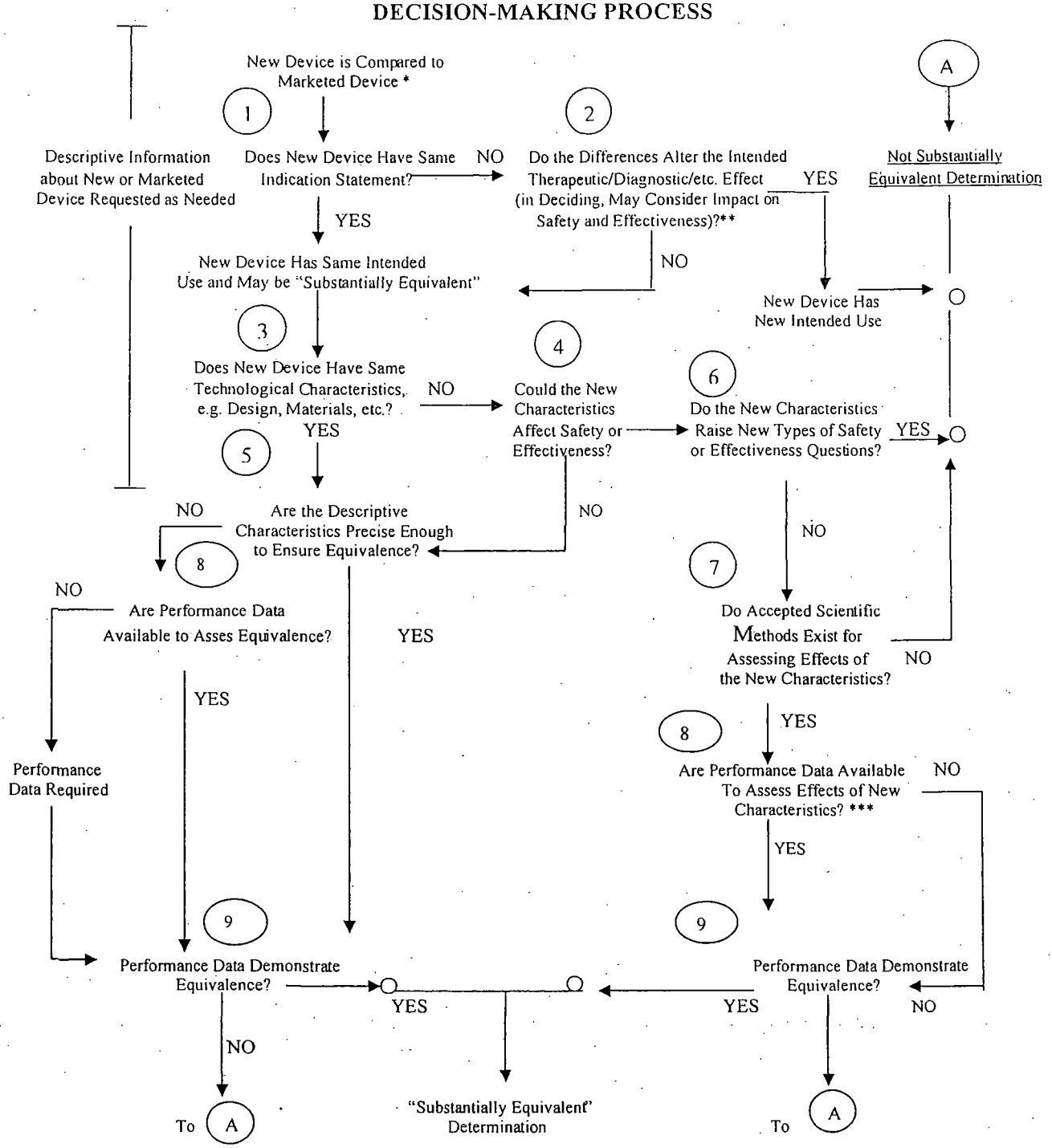
Review: (Branch Chief) GSDB1 (Branch Code) 11/13/12 (Date)

Final Review: (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K122248/S1_____

Date: November 7, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Apira Science, Inc.
Device Name: igrow Hair Rejuvenation System II
Contact: Raymond R. Blanche
Phone: 973-539-7444
Fax: 973-539-7445
Email: NSTConsultingLLC@gmail.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the igrow Hair Rejuvenation System II into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

The igrow hair growth system is a helmet type device that incorporates 21 red diode lasers and 30 red super-luminescent LED's. The helmet and light exposure system covers 1/3 of the head which corresponds to the hair growth area. The helmet has ear flaps which help correctly orient the helmet in terms of correct placement on the head and these ear flaps also contain speakers through which music can be played during the treatment session.

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?			
Is the device sterile?		X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Yes	No	N/A
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?	X		

IV. Indications for Use

It is indicated to promote hair growth in males with androgenic alopecia who have Norwood Hamilton Classification of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV.

V. Predicate Device Comparison

(b)(4) [redacted] (b)(4)

VI. Labeling

The company has provided a User Manual for the requested indication for use. (b)(4) [redacted] (b)(4) [redacted].

(b)(4) [redacted] (b)(4)

VII. Sterilization/Shelf Life/Reuse

The device is not sold sterile. Shelf life is not an issue. The company has provided information on cleaning between uses with comments related to hair oils and lotions.

VIII. Biocompatibility

The company has provided information on material used in the device. The inner lining does not come into contact with the scalp.

IX. Software

(b)(4) [redacted] (b)(4) [redacted].

(b)(4) [redacted].

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The company has provided Standards form 3654 and has stated that the device meets classification of laser equipment in accordance with IEC 60825-1 Edition 1.2, 2001-08 and IEC 60601-2-22. The company has stated conformance and testing according to IEC 60601-1 and 60601-1-2.

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

XVI. Contact History

The above deficiencies will be transmitted to (b) (6) by electronic mail and he will be informed that the application is being placed on HOLD. An effort will be made to contact him by telephone.

XVII. Recommendation HOLD
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP

Richard P. Felten
2012.11.09 08:18:28 -05'00'

Reviewer — Date

Neil R Ogden
2012.11.13 10:19:52 -05'00'

Branch Chief — Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

Date: Nov. 2, 2012

From: Mathematical Statistician: Jianxiong Chu
Division of Biostatistics, OSB

Subject: K122238 The igrow Hair Rejuvenation System II for hair loss in males.
Apira Science, Inc.

To: Richard P. Felten
ODE/DSORD/GSDB

I. Introduction

The igrow Hair Rejuvenation System II is a Low-Level Laser and Light Therapy device operating at the 655-nanometer wavelength of visible light. Exposure to the laser/light radiation will not cause the human body temperature to sustain any rise in temperature above the base normal of 37.0 degrees centigrade. The system contains an analog system, optical power output monitor that controls laser emission levels (not to exceed 5 ± 20% milliwatts), and is configured as a low-profile helmet, with functional ear phones that are used for music listening and stabilization on the head. Within the helmet are contained 21, 5-milliwatt diode lasers and 30 super luminescent diodes, affixed in an evenly distributed pattern across the inner helmet liner. The laser/light emission level is fixed at approximately 68j/cm^2 and cannot be adjusted by the user/operator. The duration of therapy is the only variable that is operator controlled. The standard therapy session is 20 or 25 minutes, depending on program selection.

(b)(4) [redacted].

(b)(4) [redacted].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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II. Summary of the Clinical Study

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

[redacted]

(b) (4)

[redacted]

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

[redacted]

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

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(b) (4)

[redacted]

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(b) (4)

[redacted]

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(b) (4)

[redacted]

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(b) (4)

[redacted]

If you have any questions concerning this review please contact me.

Jainxiong (George) Chu, Ph.D.

Cc:

Phyllis Silverman, M.S.
Medical Device File
Board File

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

OFFICE OF DEVICE EVALUATION
IDE CLINICAL REVIEW

From: Betsy Ballard, MD FACS
GSDB/DSORD/ODE

To: Richard Felton, Reviewer Requesting Consult
GSDB/DSORD/ODE

CC: Neil Ogden, Branch Chief
GSDB/DSORD/ODE

Subject: **K122248**
Igrow Hair Rejuvenation System II
Apria Sciences, Inc

Date: 10-26-2012

RECOMMENDATION: Approval

SUMMARY

This document contains a review of an original 510(k) for a device for hair restoration using a low level laser treatment.

BACKGROUND INFORMATION

Device Description (and History)

The device is a low-level laser/light system operating at 655 +/-10 nanometers. The physical configuration is that of a helmet containing an inner and outer liner, stabilized with ear phones that are fully functional for listening t musica. The system operates on line voltage at 120 or 240 volts. The helmet's inner liner permits full adjustment to any head shape by means of r 4 adjustable feet with positioning boots. The helmet contains 21, 5-milliwatt-diode lasers and 30, 5mm, through-the-hope super luminescent diodes that emit red light. The system delivers fixed laser emission levels, measured to be 68L/cm^2 for a 20 minute treatment session, which cannot be altered by the operator. The only setting the operator can make is duration of therapy.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Clinical Study Provided:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b)(4)

[redacted]

ADDITIONAL INFORMATION

Adverse events; The sponsor states there were no such events.

Case Report Forms

Reviewer's comments: *not provided*

Informed consent

Not provided

Brief Labeling Review:

Reviewer's comments: *Not available for review.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVIEW CONCLUSIONS/DISCUSSION

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

RECOMMENDATION

Based on my review of the completed clinical trial section, I recommend that this application be approved for use in males with androgenetic alopecia only.

The sponsor should address the deficiencies noted below.

(b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Felten, Richard P.

From: Felten, Richard P.
Sent: Tuesday, November 13, 2012 11:27 AM
To: Raymond R. Blanche (nstconsultingllc@gmail.com)
Subject: iGrow Hair System

Attachments: Apira igrow Helmet Hair Growth Deficiencies K122248.S1.doc

Mr. Blanche:

(b) (4)

I have attached a list of the issues that need to be addressed. I am placing the application on HOLD as of today.

I will be in meetings after 11:30 this morning but will try to contact you be telephone this afternoon.

I would appreciate it if you could send me the proposed response by electronic mail prior to sending the hard copy to the Document Control Center so that I can make sure the responses are acceptable.

Apira igrow Helmet Hair Growth...

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

November 9, 2012

Deficiencies for K122248/S1

Submitted by Apira Science, Inc.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 22, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248

Product: IGROW HAIR REJUVENATION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Sanders, Aisha *

From: Microsoft Outlook
To: nstconsultingllc@gmail.com
Sent: Monday, October 22, 2012 2:13 PM
Subject: Relayed: K122248 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

nstconsultingllc@gmail.com (nstconsultingllc@gmail.com)

Subject: K122248 AI Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

nst
CONSULTING, LLC

K122248/S001

October 5, 2012

K7

FDA CDRH DMC
OCT 22 2012
Received

Mr. Richard P. Felten
Center for Devices and Radiological Health
Document Mail Center, W066-0609
10903 New Hampshire Avenue
Silver Spring , MD 20993-0002

RE: K122248 Deficiency Letter dated September 29, 2012

Dear Mr. Felten:

(b) (4)

641 Shunpike Road, #311 Chatham, NJ 07928 Tel: 973 539 7444 Fax: 973 539 7445 Email: NSTConsultingLLC@gmail.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

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(b) (4)

[redacted]

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(b) (4)

[redacted]

On behalf of the manufacturer, I remain ready to respond to further questions and provide additional documentation in support of answers to questions.

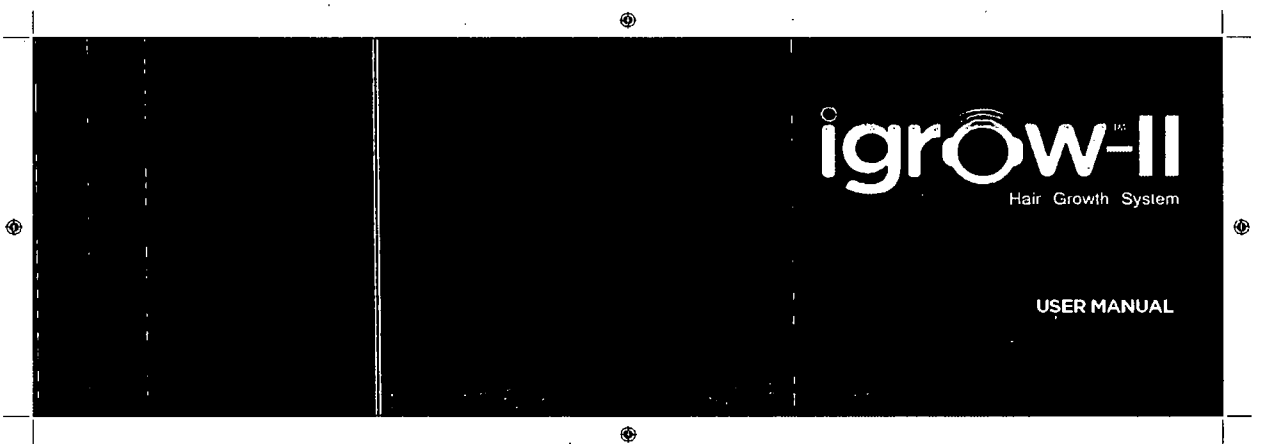
Sincerely,

Raymond R. Blanche
Clinical & Regulatory Affairs Advisor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Cover Page:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Contents Page:

Table of Contents:

iGrow-II Hair Growth System
Important Information
- Intended Usage
- Frequency of Use
- Precautions
- Contraindications
- Warnings

Components
Instructions for Use
Safety Label
Power Supply Specifications
Maintenance Instructions
Warranty
Error Messages/Troubleshooting
Corporate Information/Additional Information

Introduction Page:

Introduction:

The iGrow-II Hair Growth System is designed for hair growth. All product information and articles are intended to be for informational purposes only. The iGrow-II is cleared by the FDA for the treatment of genetic hair loss in men. Compliant use of the iGrow-II will cause hair to grow.

The iGrow-II Hair Growth System is the first hands free, home use, portable laser system available for thinning and damaged hair. The iGrow-II's design incorporates a combination of High Quality True Laser Diodes and Super Luminescent Light Emitting Diodes (LED's). This unique design provides therapeutic light to cover the entire scalp without the need for constant manual movement. The iGrow-II's hands free design makes it easy and comfortable to use, and you can listen to your favorite music from your iPod or MP3 player. Optionally, simply plug your music source into the Handheld Control Unit (E) and relax.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Information Page:

Important Information:

The iGrow-II Hair Growth System
Use of the iGrow-II Hair Growth System as instructed is for men **18 years of age (or as governed by state law) and older who have received a medical diagnosis of genetic hair loss.**
If the use of the iGrow-II is discontinued, improvements may gradually decrease. The iGrow-II has been specifically designed for ease of operation. Adherence to the guidelines and instructions provided will result in the maximum effectiveness.

Intended Usage Page:

Intended Usage:

- Read all instructions before using your iGrow-II Hair Growth System.
- The iGrow-II should be used only for the purpose described in this manual.
- The iGrow-II Hair Growth System is intended for use on the human scalp only. Use on other parts of the body is not recommended.

The iGrow-II has been fitted with an electronic protection sensor that prevents the iGrow-II from operating if the unit is not placed on the head. In the event of a malfunction do not look directly at the Helmet (A) light sources of this unit while it is in operation. If the sensor in your iGrow-II is not working properly, discontinue use and contact Apira Science, Inc. Customer Service at **1-866-982-7472** or support@igrow-II.com for repair or replacement.

- Do not scratch, mark or otherwise damage the light emitting surface.
- Do not point or shine the iGrow-II lights at others, pets, etc.
- Do not adjust or modify the iGrow-II. Use of this product or procedures other than those specified in this manual may result in injury.
- Do not put tension on the cord when untangling or straightening. This may break the cord or connections and could result in a malfunction or electrical hazard.
- Never leave the iGrow-II Hair Growth System plugged into the electrical outlet while unattended. This could cause an electrical hazard that may result in an injury.
- The iGrow-II Hair Growth System should be stored in a dry area with a temperature range of 50 - 85 degrees F. Do not store in Direct Sunlight or on hot surfaces such as radiators or heaters. Do not store the unit near to strong chemicals such as acids or bases.
- Failure to use and maintain the iGrow-II in accordance with the instructions in this manual will void the product warranty.

NOTICE: Do not attempt to repair any portion of the iGrow-II Hair Growth System. This appliance has no user-serviceable parts. If a malfunction occurs, disconnect the iGrow-II from the electrical source and contact Apira Science, Inc. at Customer Service at **1-866-982-7472** or support@igrow-II.com.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Frequency of Use Page:

Frequency of Use:

The iGrow-II Hair Growth System should be used every other day (do not use for one full day between sessions). It is not recommended for use on consecutive days. The total time of each session is **25 minutes.** Exceeding the recommended times or frequency **will not** increase the effect of the iGrow-II.

Contraindications Page:

Contraindications:

- **THE iGrow-II HAIR GROWTH SYSTEM HAS NO KNOWN CONTRAINDICATIONS OR SIDE EFFECTS OTHER THAN SENSITIVITY TO THIS SPECIFIC WAVELENGTH OF LIGHT (655nms).**

This unit is intended for men 18 years and older. It should not be used by women or children

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings Page:

Warnings:

TO REDUCE THE RISK OF ELECTRICAL SHOCK, THAT MAY CAUSE INJURY OR DEATH:

- Always attach the power supply to the unit first, and then connect the plug into outlet.
- Do not place or store the unit where it can fall or be pulled into a tub or sink.
- If the unit accidentally falls into water or other liquid, unplug it from the electrical outlet immediately. DO NOT REACH INTO OR TOUCH THE WATER.
- Avoid getting the iGrow-II Hair Growth System wet. This may result in electric shock.
- Use only the power supply provided with the iGrow-II.
- Never operate the iGrow-II if it has a damaged cord or plug. If it is not working properly or it has been dropped or damaged or submerged in water, return the product to Apira Science, Inc. for examination or repair.
- Keep the cord away from heated surfaces. Contacting a heated surface with the cord or a plug can cause the product to malfunction and produce an electrical shock.
- Always unplug the iGrow-II Hair Growth System from the power outlet immediately following use.
- Only use the iGrow-II Hair Growth System according to the instructions provided. Any other use is not recommended.

WARNING - VIEWING THE LASER OUTPUT WITH CERTAIN OPTICAL INSTRUMENTS (FOR EXAMPLE, EYE LOUPES, MAGNIFIERS AND MICROSCOPES) WITHIN THE DISTANCE OF 100MM MAY POSE AN EYE HAZARD.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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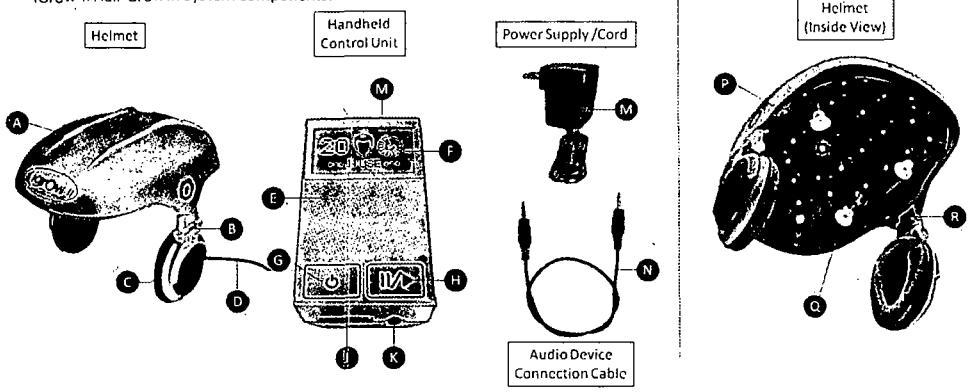
Components List Page:

Diagram 1:
iGrow-II Hair Growth System Components:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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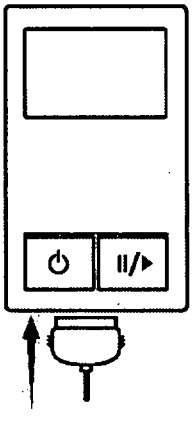
Instructions for Use Page(s):

The iGrow-II Hair Growth System should be used every other day with one day between sessions. It is not recommended for use on consecutive days. The total time of each session is 25 minutes, depending on the option selected. This duration is automatically controlled by the system. Exceeding the recommended times or frequency will not increase the effect of the iGrow-II.

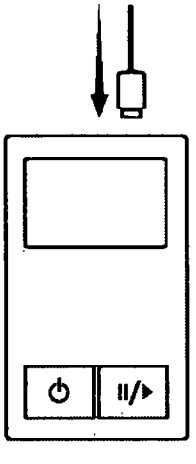
The letter references in this section refer to the part list shown previously in Diagram 1.

Step 1
Unpack the components of the **iGrow-II Hair Growth System** and make sure all the parts are present according to Diagram 1. If there are parts missing contact customer service at **1-866-982-7472** or support@igrow-II.com.

Step2
Insert the iGrow-II cable connector (D) from the iGrow-II Helmet into the port (K) on the Handheld Control Unit (E). Hold the spring clips on the side of the connector while inserting the cable into the Handheld Control Unit (E). The embossed arrow on the connector head should face upwards while viewing the top of the Handheld Control Unit (E). Do not force the connector into the port.



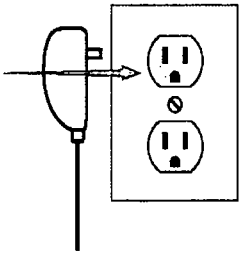
Step 3
Plug the smaller end of power supply (N) into the connection port (M) at the top of the Handheld Control Unit (E). This connector is designed to be inserted with the wider side of the connector facing the top of the Handheld Control Unit (E). Do not force the connector into the port.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

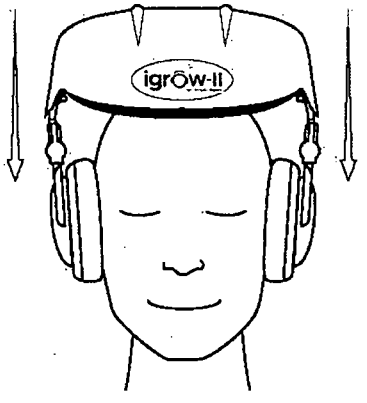
Step 4
Plug the pronged end of the power supply (N) into a convenient electrical outlet. Both a 110V and 240V prong clips are supplied. . Use the appropriate configuration for you outlet and attach the proper prong clip to the power supply..



Step 5

Fold out the retractable head phones (C) of the Helmet (A) using the retractable folding hinge (B) and place the iGrow-II Helmet (A) onto the head.

Step 6
Place the iGrow-II Helmet (A) comfortably on top of the head with the headphones (C) securely covering the ears. The iGrow-II logo should be facing forward and be visible above the forehead if viewed in a mirror. In addition, each headphone is marked left and right using letters to indicate such.

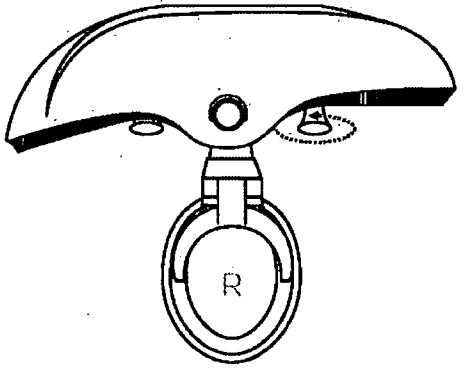


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

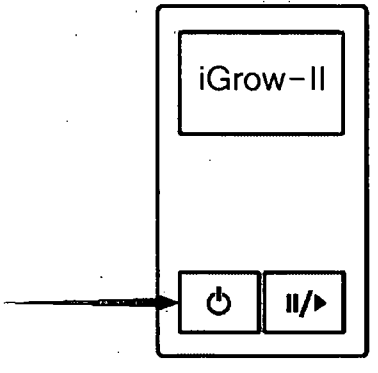
Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Step 7
The iGrow-II Helmet (A) **must** sit flat on the head. It should not be tilted to the front or the back of the head or from side to side. If needed, adjust the Helmet (A) by one of two methods.

1. Adjust the opaque rubber boot by reaching under the helmet (A) until the boots sit flat against the scalp and it sits securely on the head.
2. Each of the spacing columns (R) can be adjusted by **grasping the column base** with your fingers and turning each column base counterclockwise (longer) or clockwise (shorter) until a comfortable fit is achieved.



Step 8
Push the Power button (H) located on the iGrow-II Handheld Control Unit (E) to turn the unit **ON**. The word **"iGrow-II"** will appear on the LCD display (F) of the Handheld Control Unit (E).

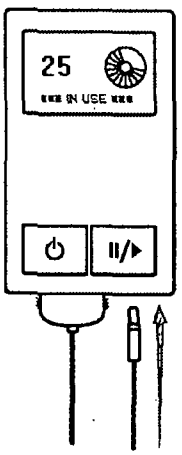


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

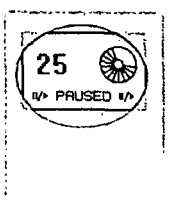
Step 9

Optionally, plug one end of the supplied audio connector cable (P) into the earphone jack of an iPod, MP3 or other compatible audio source. Plug the other end of the connector into the receptor (L) on the iGrow-II Handheld Control Unit (E). If not connected to an audio source, the headphones (C) allow for normal hearing.



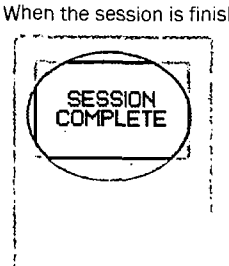
Step 10

If the iGrow-II Helmet (A) is removed from the head before the completion of a session, the Electronic Protection Sensor (S) will stop the session and the LEDs (Q) will turn off. The iGrow-II Handheld Control Unit (E) will automatically pause operation and the LCD Display (F) will indicate that the unit has been paused. To continue the session, place the iGrow-II Helmet (A) back on the head and press the pause/start button (J).



Step 11

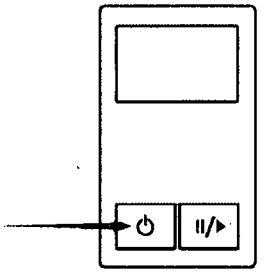
When the session is finished, **"Session Complete"** will appear on LCD Display (F).



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

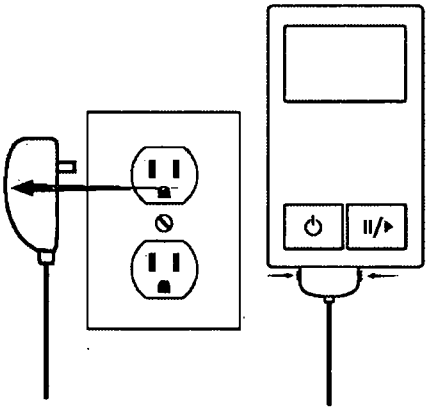
Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Step 12
Push the Power button (H) located on the iGrow-II Handheld Control Unit (E) to turn the unit **OFF**. The LCD Display will go blank indicating the power is off.



Step 13

Unplug the power supply from the electric outlet, disconnect all connector cables from the Handheld Control Unit (E), and remove the Helmet (A). Depress the springs on the connector end of the cable (D) for the Handheld Control Unit (E) when removing. Pulling this cable out without depressing these springs can cause permanent damage to the unit. Properly store your iGrow-II System in accordance with the recommendations listed in the warning section above.



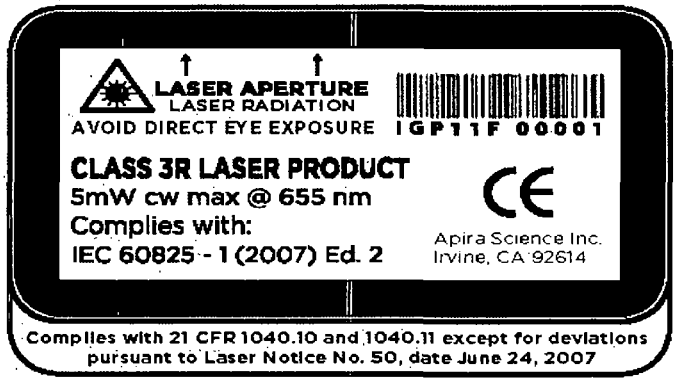
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Safety Label Page:

Safety Label

The following laser safety label can be found on the inner canopy of the Helmet (A).



Wavelength: 655 +/- 5nm

Visible Red Light - Class 3R

The iGrow-II Laser Hair Growth System complies with IEC 60825 - 1 Ed. 2 (2007) standards

The lasers of the iGrow-II are classified as "Class 3R". The iGrow-II gives off no heat or harmful radiation, causes no pain and does not require the use of drugs or topicals.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Power Supply Specifications Page:

POWER SUPPLY SPECIFICATIONS

Output from the transformer: 5V
Audio Jack: 3.5mm

The power supply for the iGrow-II Hair Growth System has been designed for use in the United States and Internationally. The power supply will adapt to 110 Volt/60 cycles (US) or 240 volt/50 cycles. If the power outlets in your country use plugs different than the type supplied with the iGrow-II, it will be necessary to obtain an appropriate country specific plug adaptor (these are not supplied with this unit).

Maintenance Instructions Page:

The iGrow-II is designed to provide years of trouble free operation. If it is necessary to clean the unit surfaces please follow these instructions. Note: the iGrow-II has no parts that can be serviced by the user. If service is required, contact Apira Science, Inc.

ALWAYS UNPLUG THE iGrow-II HAIR GROWTH SYSTEM FROM THE POWER OUTLET BEFORE CLEANING IT.

DO NOT use Acetone or any other solvents on any part of the iGrow-II. Acetone and other solvents will damage the unit and void the warranty.

To clean the iGrow-II, gently apply a soft microfiber cloth to the surfaces. Extra care must be taken to clean the underside of the unit around the light sources. Do not use excessive pressure or force as this may damage the iGrow-II unit.

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in direct radiation exposure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 02, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248
Product: IGROW HAIR REJUVENATION SYSTEM
On Hold As of 10/1/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FDA Freedom of Information Act, 5 U.S.C. 552, as amended. Released by CDRH on 09-29-2015

Please remember that the Safe Medical Devices Act of 1990 requires that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Chin, Yeuly *

›m: Microsoft Outlook
ı o: nstconsultingllc@gmail.com
Sent: Tuesday, October 02, 2012 3:06 PM
Subject: Relayed: K122248 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

nstconsultingllc@gmail.com (nstconsultingllc@gmail.com)

Subject: K122248 Hold Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Richard R. Fetten

Subject: 510(k) Number K122248

To: The Record

Please list CTS decision code HOLD

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold). Electronic Mail 10/1/12

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*	N/A	
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
890.5800	II	OAP

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

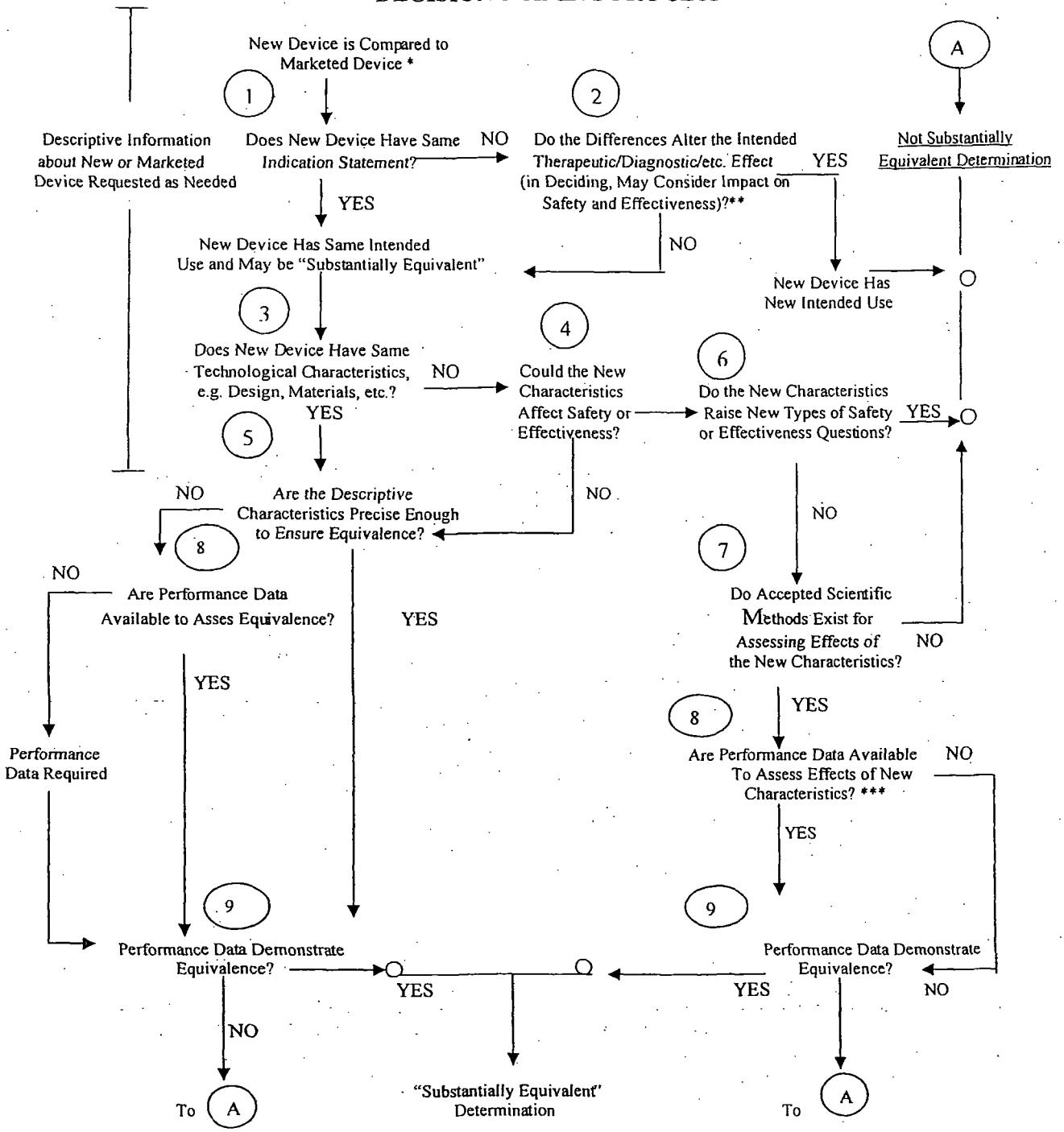
Review: Neil R.P. Ogden (Branch Chief) GSDB (Branch Code) 10/1/12 (Date)

Final Review: (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K122248_____

Date: September 29, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Apira Science, Inc.
Device Name: igrow Hair Rejuvenation System
Contact: Raymond R. Blanche
Phone: 973-539-7444
Fax: 973-539-7445
Email: NSTConsultingLLC@gmail.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the igrow Hair Rejuvenation System into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?			
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

IV. Indications for Use

It is indicated to promote hair growth in males with androgenic alopecia who have Norwood Hamilton Classification of IIa to V and Fitzpatrick Classification of Skin Phototypes I to IV.

V. Predicate Device Comparison

(b)(4) [redacted] (b)(4) .

VI. Labeling

The company has provided a User Manual for the requested indication for use. (b)(4) [redacted] (b)(4) .

VII. Sterilization/Shelf Life/Reuse

The device is not sold sterile. Shelf life is not an issue. The company has provided information on cleaning between uses with comments related to hair oils and lotions.

VIII. Biocompatibility

The company has provided information on material used in the device. The inner lining does not come into contact with the scalp.

IX. Software

(b)(4) [redacted]

	Yes	No
Version:		
Level of Concern:		
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The company has provided Standards form 3654 and has stated that the device meets classification of laser equipment in accordance with IEC 60825-1 Edition 1.2, 2001-08 and IEC 60601-2-22. Also have listed conformance and testing according to IEC 60601-1 and 60601-1-2.

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

XIII. Performance Testing – Clinical

(b)(4)

[redacted]

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

[redacted]

XVI. Contact History

Mr. Blanche was previously contacted regarding the original application requesting over-the-counter clearance. Mr. Blanche provided a revised stand alone indication for use page changing this to prescription use.

He was contacted by telephone and electronic mail on Monday, October 1, 2012 and the above issues were discussed with him. He was informed that we were placing the application on HOLD to conserve review time. We do not expect that this will significantly delay the final decision but does allow time for final clarifications of any issues. If we do not have this time built into the final review then it is possible that we will not make the required 90 review clock or may not have time to raise additional question that would need to be addressed in order to make a final decision.

XVII. Recommendation HOLD
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP

Richard P. Felton — Oct 1, 2012
Reviewer — Date

Branch Chief — Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

September 28, 2012

Review of K122248

Submitted by NST Consultants
for Apira Science, Inc.

Reviewed by Richard P. Felten, DSORD, GSDB

Richard P. Felten

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

It is recommended that the above issues be conveyed to the sponsor while the clinical data is evaluated both statistically and clinically. This will allow the sponsor to make major improvements in the user manual and address several device related issues while the clinical data is being addressed and allow time following the clinical review, if needed, to clarify follow-up issues.

The sponsor was contacted by telephone on October 1, 2012 and informed that the application was being placed on HOLD. A list of questions were developed from the above list of deficiencies and these were communicated to the sponsor by electronic mail.

I recommend that this application be placed on HOLD.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

September 29, 2012

Deficiencies for igrow Hair Rejuvenation System

Apira Science K122248

Reviewed by Richard P. Felten. DSORD, GSDB

Concur 10/1/12

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b) (4)

[redacted]

It is important that in reviewing your User Manual to address some of the above issues that you make sure that any language that would appear to reflect over-the-counter uses be deleted or revised to conform to language more applicable to a prescription use device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Felten, Richard P.

To: Raymond R. Blanche (nstconsultingllc@gmail.com)
Subject: igrow K122248

Attachments: Apira igrow Helmet Hair Growth Deficiencies K122248.doc

Mr. Blanche:

(b) (4)

I will be placing the application on HOLD today. You will need to send your responses in hard copy to the Document Mail Center.

As I mentioned I will be out of the office Wednesday thru Friday of this week but should have access to electronic mail most of the time if you have questions.

Apira igrow Helmet Hair Growth...

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 27, 2012

APIRA SCIENCE, INC.
C/O NST CONSULTING, LLC
641 SHUNPIKE RD, STE 311
CHATHAM, NEW JERSEY 07928
ATTN: RAYMOND R. BLANCHE

510k Number: K122248

Received: 7/27/2012

Product: IGROW HAIR REJUVENATION SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" 'ttp://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissio s/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice ttp://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Mcdonald, Lisa *

From: Microsoft Outlook
To: nstconsultingllc@gmail.com
Sent: Friday, July 27, 2012 2:33 PM
Subject: Relayed: K122248 ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

nstconsultingllc@gmail.com

Subject: K122248 ACK Letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

INDICATIONS FOR USE

510(k) Number: K 122248

Device Name: igrow Hair Rejuvenation System II

Indications for Use:

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

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

_____ _____ _____ _____

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use __X__ OR Over-the -Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Felten, Richard P.

From: NST Consulting, LLC [nstconsultingllc@gmail.com]
Sent: Tuesday, August 21, 2012 4:41 PM
To: Felten, Richard P.
Subject: Re: K122248
Attachments: INDICATIONS FOR USE STATEMENT 2.doc

Mr. Felten:

I apologize. I have attached a word document, which should have been attached previously.

(b)(4) [redacted] ?

Best regards,

Raymond Blanche

On Tue, Aug 21, 2012 at 2:47 PM, Felten, Richard P. <Richard.Felten@fda.hhs.gov> wrote:

Mr. Blanche:

I was unable to open the attachment. I am not sure if this is an issue because of our fire wall or not. Could you send the statement simply as a Word Document.

Thank you.

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

From: NST Consulting, LLC [mailto:nstconsultingllc@gmail.com]
Sent: Friday, August 10, 2012 10:42 AM
To: Felten, Richard P.
Subject: K122248

Dear Mr. Felten:

(b)(4) [redacted]
(b)(4) [redacted] Please accept this revision, as the modification to the submission you

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

(b)(4) [redacted] Any help you can provided to us will be greatly appreciated and to be frank, quite essential, as we are unfamiliar with this pathway.

Thank you for your cooperation.

Sincerely,

Raymond Blanche

Raymond R. Blanche
NST Consulting, LLC
641 Shunpike Rd., #311
Chatham, New Jersey 07928
Tel: 973-417-8675
Fax:973-539-7445
Email: NSTConsultingLLC@gmail.com

--
Raymond R. Blanche
NST Consulting, LLC
641 Shunpike Rd., #311
Chatham, New Jersey 07928
Tel: 973-417-8675
Fax:973-539-7445
Email: NSTConsultingLLC@gmail.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Felten, Richard P.

From: NST Consulting, LLC [nstconsultingllc@gmail.com]
Sent: Friday, August 10, 2012 10:42 AM
To: Felten, Richard P.
Subject: K122248
Attachments: Intened Use Statement. Rev 2..wps

Dear Mr. Felten:

(b)(4)

[redacted]

Thank you for your cooperation.

Sincerely,

Raymond Blanche

Raymond R. Blanche
NST Consulting, LLC
641 Shunpike Rd., #311
Chatham, New Jersey 07928
Tel: 973-417-8675
Fax:973-539-7445
Email: NSTConsultingLLC@gmail.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Apira Science , Inc.

510(k) Submission for the **igrow Hair Rejuvenation System II**

July 20, 2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Section 1

Medical Device User Fee Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Form Approved: OMB No 0910-511 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

APIRA SCIENCE INC
2601 Main Street
Suite 530
Irvine CA 92614
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) (4)

2. CONTACT NAME
Raymond Blanche

2.1 E-MAIL ADDRESS
nstconsultingllc@gmail.com

2.2 TELEPHONE NUMBER (include Area code)
973-539-7444

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
973-539-7445

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (*All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within* 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4) 20-Jun-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Section 2

CDRH Premarket Review Submission Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
July 20, 2012	(b) (4)	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Apira Science, Inc.	Establishment Registration Number *(if known)*:		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 954-649-4304		
Street Address: 1200 N. Federal Highway, Suite 221	FAX Number *(including area code)*: 561-431-2609		
City: Boca Raton	State / Province: Florida	ZIP/Postal Code: 33432	Country: USA
Contact Name: Jeffrey S. Braile			
Contact Title: Director	Contact E-mail Address: jbraile@apirascience.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: NST Consulting, LLC			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 973-539-7444		
Street Address: 641 Shunpike Rd., Suite 311	FAX Number *(including area code)*: 973-539-7445		
City: Chatham	State / Province: New Jersey	ZIP Code: 07928	Country: USA
Contact Name: Raymond R. Blanche			
Contact Title: Managing Member	Contact E-mail Address: nstconsultingllc@gmail.com		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
FDA Publishing Services (301) 443-6740 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OAP	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K060305	1	Hairmax Lasercomb	1	Lexington International
2	K093499	2	Hairmax Lasercomb	2	Lexington International
3	K103368	3	Hairmax Lasercomb	3	Lexington International
4	K110233	4	Hairmax Lasercomb	4	Lexington International
5	K111714	5	Hairmax Lasercomb	5	Lexington International
6	K091496	6	MEP-90	6	Midwest RF

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Laser, comb, hair

	Trade or Proprietary or Model Name for This Device		Model Number
	igrow Hair Rejuvenation System II	1	igrow Hair Rejuvenation System II
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OAP	21 CFR 890.5500	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
General & Plastic Surgery		

Indications *(from labeling)*

Promoting hair growth in males with androgenetic alopecia who have Norwood-Hamilton classifications of IIa-V and Fitzpatrick skin phototypes of I- IV.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Note: Submission of this form does not mean that you are required need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION I UTILIZATION OF STANDARDS

Records processed under FOIA Request # 2013-0000, Released by CDRH on 00-00-2013

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC-60825-1	IEC	Classification of Laser equipment	Edition 1.2	01/01/2001
2	IEC 60825-1	IEC	Safety of laser products- Part 1 : Equipment classification and requirements	Edition 2	03/01/2007
3	SS-EN-60825-1	IEC	Standards of Allowable Emission Levels	None	01/01/1994
4	IEC-60601-1	IEC	Medical Electronic Equipment	Edition 3	07/01/2012
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Section 3

510(k) Cover Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

K122248

A P I R A

July 20, 2012

FDA CDRH DMC
JUL 27 2012
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ATT: Abbas Bandukwala

RE: New, Traditional 510(k) Premarket Notification Submission for the **igrow Hair Rejuvenation System II**

Dear Mr. Bandukwala:

NST Consulting, LLC, is making this submission on behalf of the sponsor, Apira Science, Inc. Apira is the commercial entity that intends to market the device. The contact person for this submission is Raymond R. Blanche, an independent consultant contracted by Apira to make this submission. He may be contacted at:

NST Consulting, LLC
641 Shunpike Road, Suite 311
atham, NJ 07928
T. 973-539-7444
F. 973-539-7445
Email. NSTConsultingLLC@gmail.com

The igrow Hair Rejuvenation System II is a **Low-Level Laser Therapy** device operating at 655 nanometers. It is a class IIIa laser by international classification standards as recognized by the FDA and also a 3R class by European standards.

Pursuant to Part 21 CFR 807.95, the FDA may disclose the existence of this premarket notification submission.

The sponsor requests that this device receive the classification product code **OAP.** The Hairmax Lasercomb is the first device cleared in this category and the most accurate predicate for which comparison will be made. There are other devices that have been cleared with this classification, which are listed as predicate devices. However, they are listed for purposes of reference only, in the area of design. The MEP -90 device is offered because it demonstrates that a helmet design , in addition to a comb is a cleared form of the OAP device. The 510(k) number for the Hairmax Lasercomb is K060305 and for the MEP-90 is K091496. This request conforms to Part 21 CFR 890.5500.

The igrow Hair Rejuvenation System II should be classified as a class II medical device, for a OTC use only pursuant to Part 21 CFR 801 Subpart C. The appropriate panel is General & Plastic Surgery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

The enclosed documentation is submitted, in support of the request by the sponsor to receive marketing clearance for the igrow Hair Rejuvenation System, based upon its substantial equivalence to the Hairmax Lasercomb, K060305. ,rsuant to Part 21 CFR 807.92 (a)(3). The sponsor believes the igrow Hair Rejuvenation System II demonstrates an extremely low level of risk to subjects receiving the therapy and a commensurate level of therapeutic efficacy to the Hairmax Lasercomb. It is the opinion of the sponsor that the difference between the Hairmax Lasercomb and the igrow Hair Rejuvenation System II is physical configuration only. The MEP-90, K 091496, satisfies the question of physical design in that it and the igrow are both helmet style devices. A comparison chart of the Hairmax Lasercomb and igrow Hair Rejuvenation system II is included in Section 10 of this submission entitled, Substantial Equivalence Discussion.

Therefore, the sponsor requests marketing clearance for the intended use of promoting hair growth in males with androgenetic alopecia who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Phototypes I to IV.

Very truly yours,

Raymond R. Blanche
Clinical & Regulatory Affairs Consultant
NST Consulting LLC
On Behalf of: Apira Science, Inc.

APIRA SCIENCE, Inc. ● 2601 Main Street • Suite 530 • Irvine • California 92614 • www.igrowlaser.com • Office: +1 949.854.9900 • Fax: +1 949.854.9922

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4

Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

INDICATIONS FOR USE

510(k) Number: K_____

Device Name: igrow Hair Rejuvenation System II

Indications for Use:

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

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

_____ _____ _____ _____

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use _____ OR Over-the -Counter Use _X_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 5

510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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: Facsimile:	(973-539-7444 (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name:	igrow Hair Rejuvenation System II
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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use / Indications for Use

The igrow Hair Rejuvenation System II 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 Hair Rejuvenation System II 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 Hair Rejuvenation System II, 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 Hair Rejuvenation System II, 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,

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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 Hair Rejuvenation System II functioned as anticipated and hair re-growth was observed to be significantly greater than that of the incandescent placebo system.

Substantial Equivalence

The igrow Hair Rejuvenation System II 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 Hair Rejuvenation System II 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 Hair Rejuvenation System II 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 Hair Rejuvenation System II, 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 Hair Rejuvenation System II) 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 Hair Rejuvenation System II for OTC Use, according to Part 21 CFR 801 Subpart C). For these reasons, the igrow Hair Rejuvenation System II 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 Hair Rejuvenation System II, are substantially equivalent to the Hairmax Lasercomb .

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The clinical data presented by the sponsor for the igrow Hair Rejuvenation System II further validates that red light lasers are effective in promoting hair growth and does not present any safety issues. Therefore, the igrow Hair Rejuvenation System II satisfied the FDA's substantial equivalence criteria. Thus, the FDA should clear the device via the 510(k) notice containing clinical data.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 6

Truthful and Accuracy Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification Truthful and Accurate Statement

I certify that, in my capacity as the Chief Operating Officer of Apira Science, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material has been omitted.

Signature

Morgan Pepitone

July 20, 2012
Date

Premarket Notification [510(k)] Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7

Financial Certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6)

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Morgan Pepitone	Chief Operating Officer
FIRM/ORGANIZATION Apira Science, Inc.	
SIGNATURE	DATE *(mm/dd/yyyy)* 06/27/2012

Paperwork Reduction Act Statement

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 control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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Section 8

Executive Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

EXECUTIVE SUMMARY

The igrow Hair Rejuvenation System II

The igrow Hair Rejuvenation System II is a Low-Level Laser and Light Therapy device operating at the 655-nanometer wavelength of visible light. A low-level laser/light therapy device is one in which exposure to the laser/light radiation will not cause the human body temperature to sustain any rise in temperature above the base normal of 37.0 degrees centigrade. The laser system is classified as a IIIa/3R laser by the IEC. The system is configured as a low-profile helmet, with functional ear phones that are used for music listening and stabilization on the head. Within the helmet are contained 21, 5-milliwatt diode lasers and 30 super luminescent diodes, affixed in an evenly distributed pattern across the inner helmet liner. The laser/light emission levels cannot be adjusted by the user/operator. It is fixed at approximately 68j/cm2. The duration of therapy is the only variable that is operator controlled. The standard therapy session is 20 or 25 minutes, depending on program selection. The igrow Hair Rejuvenation System II contains an analog system, optical power output monitor that controls laser emission levels, not to exceed 5 milliwatts, plus or minus 20%. Any emission levels deviate from the allowable levels for a class IIIa/3R will cause the immediate shut down of the system. A Photodiode sensor is located within the pathway of the human head to control all emissions. The laser/light will not emit radiation unless the head is properly positioned within the helmet and will cause the therapy to PAUSE, if moved out of proper position, until the head is re-positioned correctly. This feature prevents therapy sessions from being performed in an inadequate manner or permitting use, if the helmet is not properly positioned on the head.

Device Comparison

There is only one true or ideal, predicate device in the classification product code category of OAP. Although there are nine (9) listed in the OAP classification, it is the Hairmax Lasercomb that represents a true predicate.. For purposes of comparative analysis, the following side-by-side comparison is presented.

The igrow Hair Rejuvenation System II*	The Hairmax Lasercomb – Premium
21, 5-milliwatt diode lasers 30, 5mm super luminescent diodes	9, 4milliwatt diode lasers
helmet design	hair comb design
automated, precise pattern of delivery individual user	variable, individual pattern of delivery dependent upon
algorithm controlled and non-variable	variable delivery of energy – individual combs his/her hair for a specified, period of time 15 to 45 minutes daily
655nm. wavelength of light	650-660 wavelength of light
class IIIa/3R laser – as determined by AEL	class IIIa/3R laser – as determined by AEL
Low-Level Laser and Light Therapy device	Low-Level Laser Therapy device

*Performance Testing
Kenneth J. Puckett, LSO ,Laser Product Safety LLC,CARAT Laboratory,3290A Green Level West Rd.,Cary, NC 27519 USA performed analysis and testing of the laser diode modules and determined that they conform to IEC – 60825-1 Edition 1.2 2001-08 for a class IIIa/3R laser. The European standard is class 2M.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Full Report is available in the Electromagnetic Compatibility and Electrical Safety section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9

Device Description

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DEVICE DESCRIPTION

The igrow Hair Rejuvenation System II is a low-level laser/light system operating at 655 +/-10 nanometers. The physical configuration is that of a helmet containing an inner and outer liner, stabilized with ear phones that are fully functional for listening to music. The system operates on line voltage at 120 or 240 volts. The helmet's inner liner permits full adjustment to any head shape by means of 4 adjustable feet with positioning boots. The helmet contains 21, 5-millwatt-diode lasers and 30, 5mm, through-the- hole super luminescent diodes, that emit red light. This system delivers fixed laser emission levels, measured to be 68J/cm2 for a 20 minutes treatment session, which cannot be altered by the operator. The only setting that the operator can make is duration of therapy. At the time of this submission, 20 or 25 minutes is the standard operating duration of therapy for all subjects, selectable with the hand controller.

The device helmet is constructed of an ABS type plastic. The igrow Hair Rejuvenation System II is a hands free system, requiring no active processes by the user, other than starting a therapy session. Only the laser and LED light contacts the human scalp, emitted directly from the inner liner, without any focusing lens system. The device helmet covers the upper one-third of the head, with orientation from the bridge of the nose in the anterior, toward the occipital notch in the posterior and from the upper most portion of the ear on both sides of the head. When operated correctly, the helmet remains approximately 2 – 4 centimeters away (based upon head size) from the scalp.

There is no maintenance schedule for the operator to perform other than maintaining a clean, inner liner and external energy source surfaces. Simple disinfectant wipes that are commercially available are adequate for cleaning the plastic liner and cotton tipped swaps that have been saturated with 90% alcohol are most suitable for the external diode surfaces, should they become covered with scalp oils or hair lotion.

There are no accessories for this system, no safety devices required by regulation or international standard, no biocompatible hazards or concerns, no optional models or consumable products. The igrow Hair Rejuvenation System II is offered as one model choice only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10

Substantial Equivalence

With Clinical Performance Testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUBSTANTIAL EQUIVALENCE DISCUSSION

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Conclusion:

Technologically and clinically, the igrow Hair Rejuvenation is substantially equivalent to the Hairmax Lasercomb based upon the data presented in this report, specifically, the Clinical Trial and side by side comparison of the two devices. The sponsor requests that a Marketing Clearance be granted to the igrow Hair Rejuvenation System based on its substantial equivalence to the Hairmax Lasercomb (K060305).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 11

Proposed Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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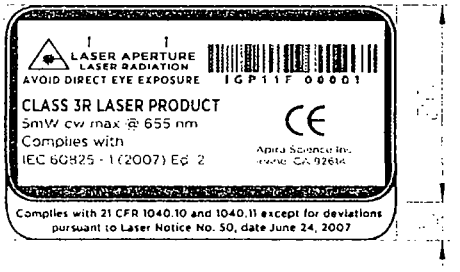
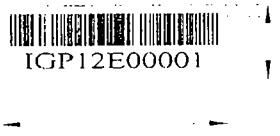
LABELING FOR THE
igrow Hair Rejuvenation System



Located on inner liner of helmet, posterior

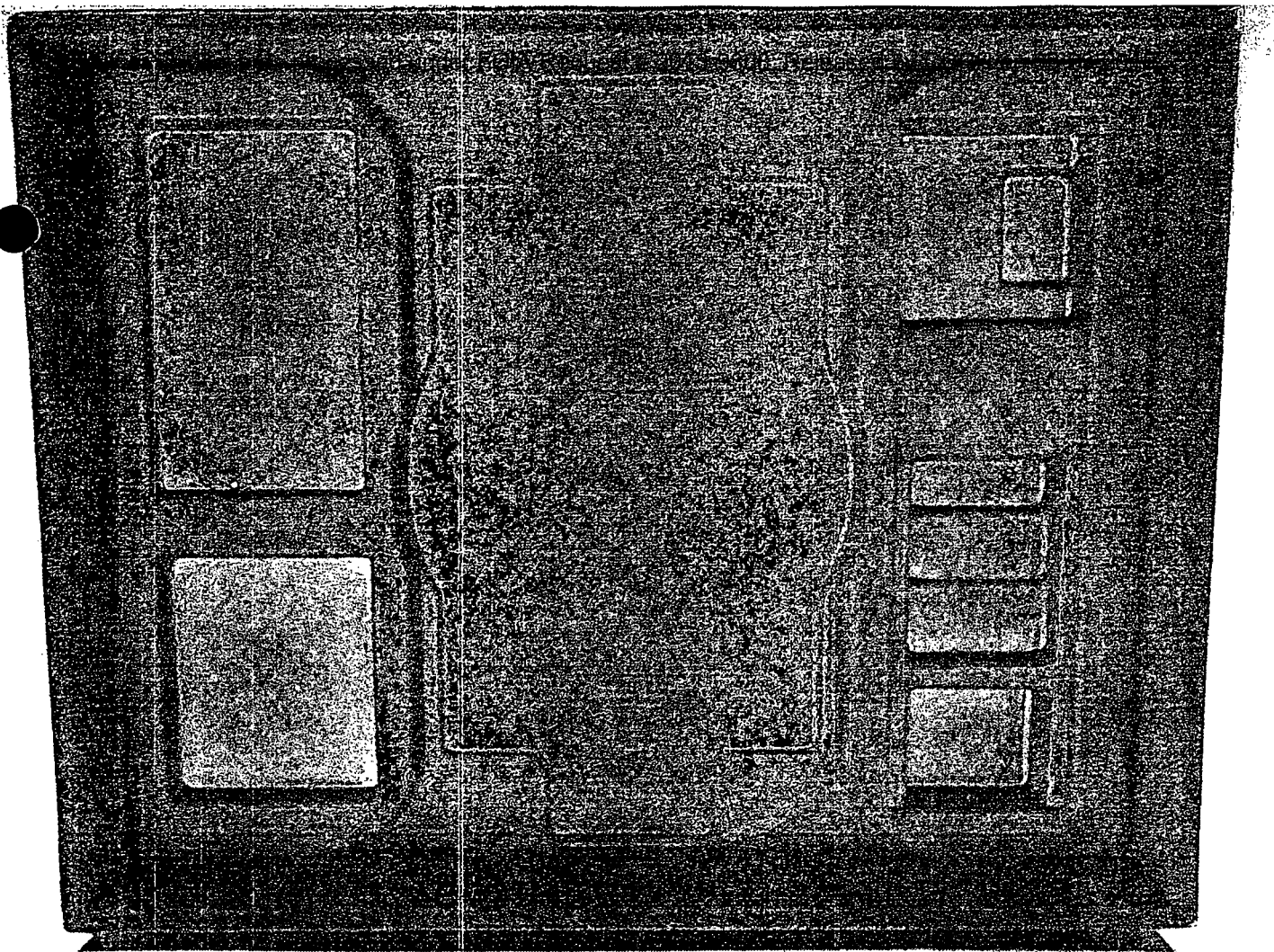
Designed in California by:
Apira Science, Inc.
Assembled in China

Located on posterior of hand controller



Located on posterior of hand controller
and on posterior of inner liner of helmet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



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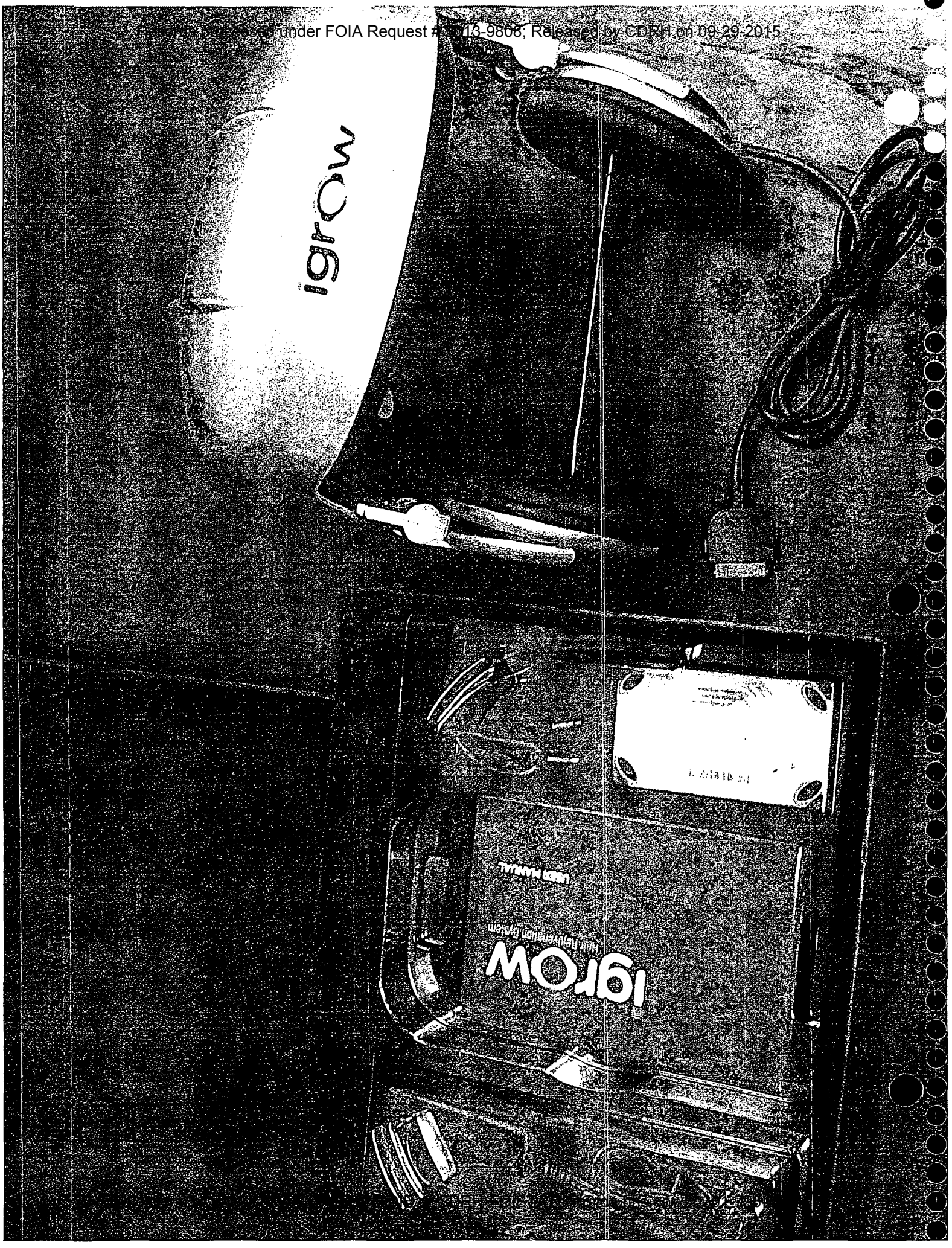
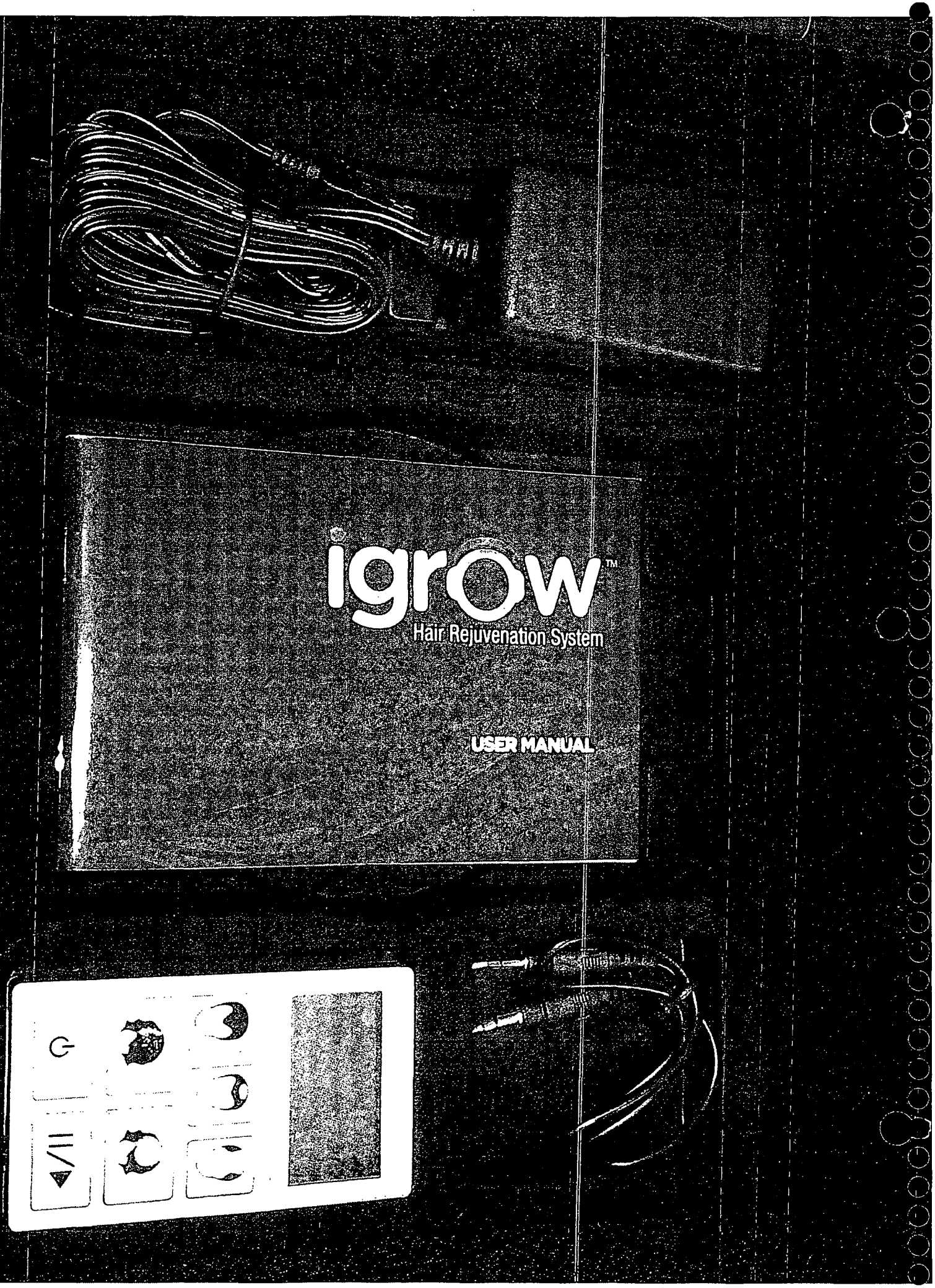
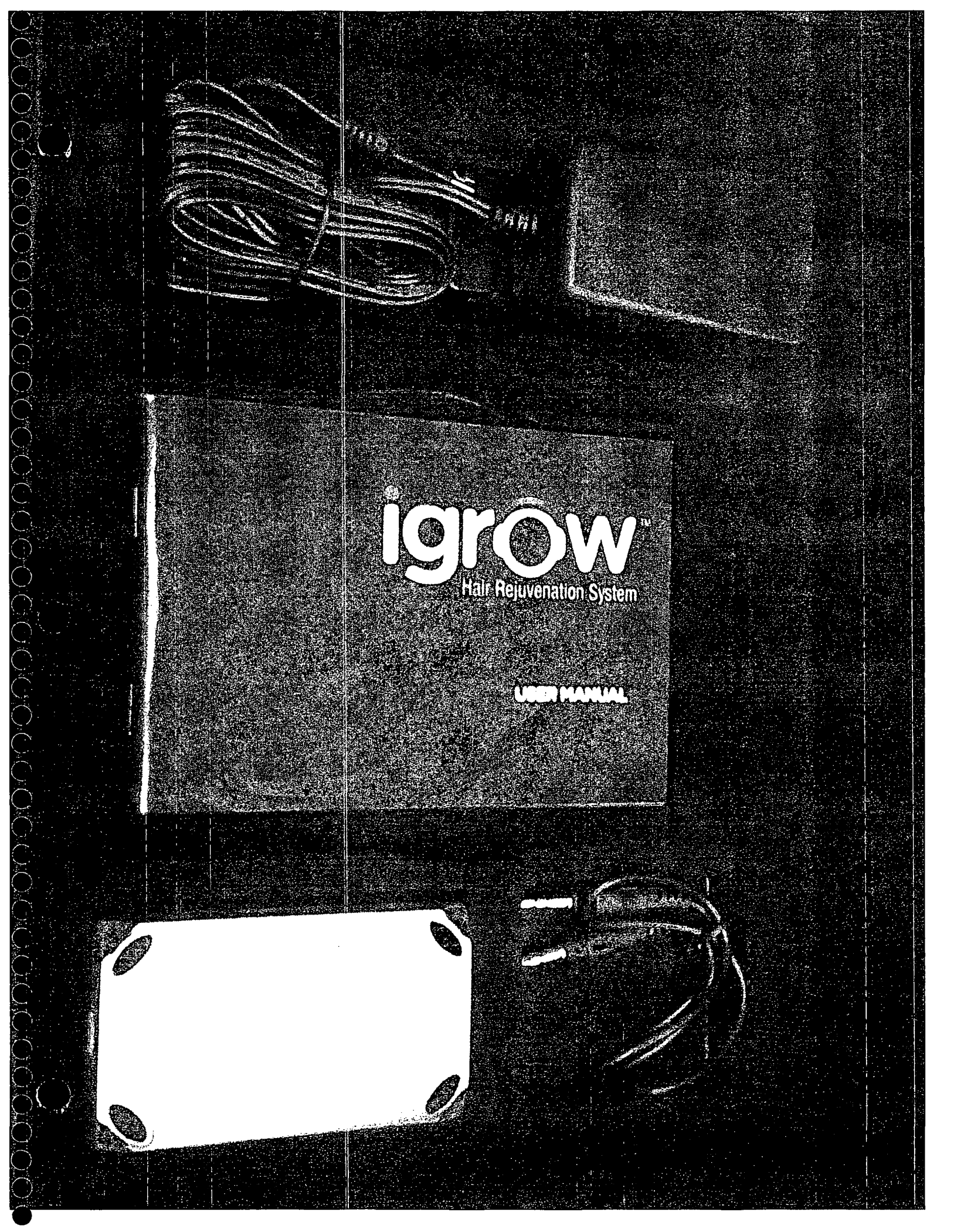



igrow™
Hair Rejuvenation System
USER MANUAL


igrow™
Hair Rejuvenation System
USER MANUAL

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IGROW

USER MANUAL

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Section 12

Electromagnetic Compatibility and Electrical Safety

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The igrow Hair Rejuvenation System conforms to the standard IEC-60825-: 2007-03 in testing performed by (b)(4) [redacted]. Testing was performed on the current igrow model. The IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal Register, July 26, 2001 (volume 66, Number 144) [page 39049 39050].

The results from (b)(4) [redacted] and a copy of the Federal Register pages are contained herein.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Apira Science Inc.
100 Bayview Circle Suite 2200
Newport Beach, CA 92660

Model igrow

TEST RECORD

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Section 13

Performance Testing, Clinical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 14

Statistical Methods and Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 15

Software

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SOFTWARE

The igrow Hair Rejuvenation System II is an analog system. To achieve conformance to 21 CFR 1040.11 for maintaining a fail-safe procedure to prevent variations in laser output above or below the 5 milliwatt limitation of a class IIIa (3R) laser, the following procedure report is provided.

This report has been copied from the (b)(4) [redacted].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 16

Operator's Manual - igrow Hair Rejuvenation System II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cover Page:

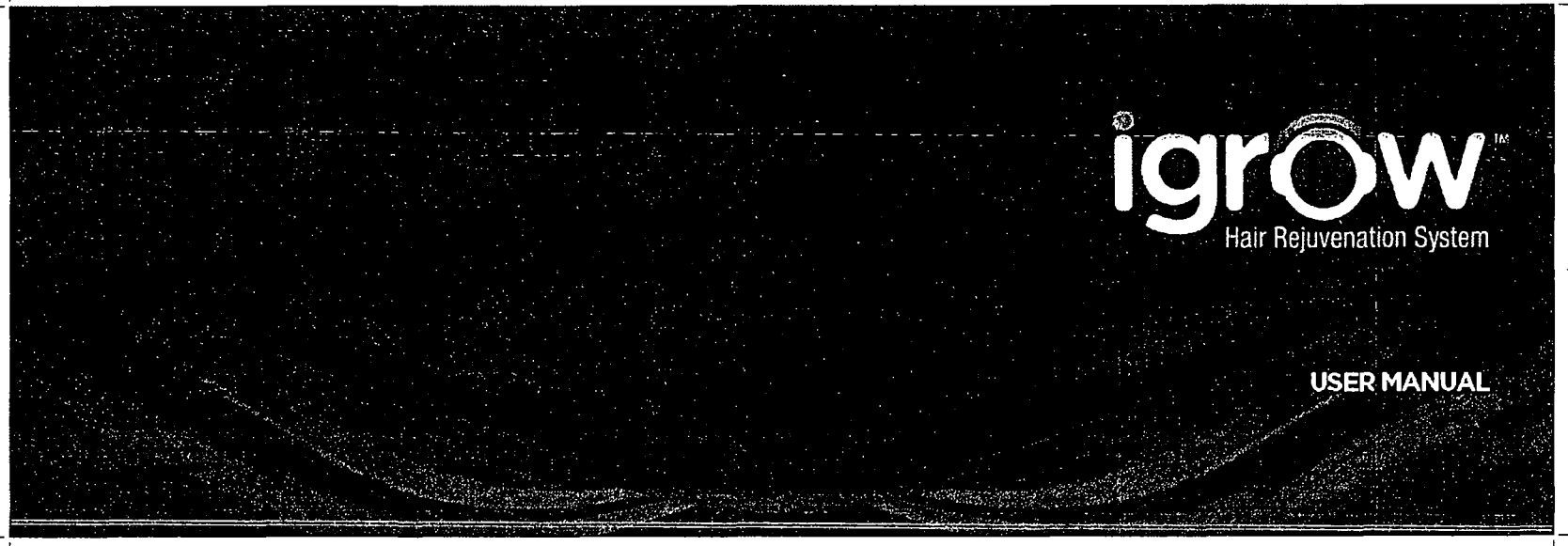

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Table of Contents:

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Important Information
- Intended Usage
- Frequency of Use
- Precautions
- Contraindications
- Warnings

Components
Instructions for Use
Safety Label
Power Supply Specifications
Maintenance Instructions
Warranty
Error Messages/Troubleshooting
Corporate Information/Additional Information

Introduction Page:

Introduction:

The iGrow Hair Rejuvenation System is designed for hair wellness and general hair rejuvenation. All product information and articles are intended to be for informational purposes only. The iGrow is cleared by the FDA for the treatment of genetic hair loss in men. Compliant use of the iGrow will cause hair to regrow. Other benefits may be thicker, stronger, darker hair and a healthier scalp, although there is no clinical data to support these effects.

The iGrow Hair Rejuvenation System is the first hands free, home use, portable laser system available for thinning and damaged hair. The iGrow's design incorporates a combination of High Quality True Laser Diodes and Super Luminescent Light Emitting Diodes (LED's). This unique design provides therapeutic light to cover the entire scalp without the need for constant manual movement. The iGrow's Automated Handheld Control Unit (E) provides 3 individual program modes that allow you to customize your session. These modes are programmed for specific patterns of thinning hair in men. Each setting is designed to maximize the effect of the iGrow on the selected area of the scalp. The iGrow's hands free design makes it easy and comfortable to use, and you can listen to your favorite music from your iPod or MP3 player. Optionally, simply plug your music source into the Handheld Control Unit (E) and relax.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Information Page:

Important Information:

The iGrow Hair Rejuvenation System

Use of the iGrow Hair Rejuvenation System as instructed is all it takes to see thicker fuller hair in men **18 years of age (or as governed by state law) and older who have received a medical diagnosis of genetic hair loss.**

The iGrow Hair Rejuvenation System, when used on a regular basis, can make the hair visibly thicker in as little as six weeks. If the use of the iGrow is discontinued, improvements may gradually decrease. The iGrow has been specifically designed for ease of operation. Adherence to the guidelines and instructions provided will result in the maximum effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Usage Page:

Intended Usage:

- Read all instructions before using your iGrow Hair Rejuvenation System.
- The iGrow should be used only for the purpose described in this manual.
- The iGrow Hair Rejuvenation System is intended for use on the human scalp only. Use on other parts of the body is not recommended.

The iGrow has been fitted with an electronic protection sensor that prevents the iGrow from operating if the unit is not placed on the head. In the event of a malfunction do not look directly at the Helmet (A) light sources of this unit while it is in operation. If the sensor in your iGrow is not working properly, discontinue use and contact Apira Science, Inc. Customer Service at **1-866-982-7472** or support@igrowlaser.com for repair or replacement.

- Do not scratch, mark or otherwise damage the light emitting surface.
- Do not point or shine the iGrow lights at others, pets, etc.
- Do not adjust or modify the iGrow. Use of this product or procedures other than those specified in this manual may result in injury.
- Do not put tension on the cord when untangling or straightening. This may break the cord or connections and could result in a malfunction or electrical hazard.
- Never leave the iGrow Hair Rejuvenation System plugged into the electrical outlet while unattended. This could cause an electrical hazard that may result in an injury.
- The iGrow Hair Rejuvenation System should be stored in a dry area with a temperature range of 50 - 85 degrees F. Do not store in Direct Sunlight or on hot surfaces such as radiators or heaters. Do not store the unit near to strong chemicals such as acids or bases.
- Failure to use and maintain the iGrow in accordance with the instructions in this manual will void the product warranty.

NOTICE: Do not attempt to repair any portion of the iGrow Hair Rejuvenation System. This appliance has no user-serviceable parts. If a malfunction occurs, disconnect the iGrow from the electrical source and contact Apira Science, Inc. at Customer Service at **1-866-982-7472** or support@igrowlaser.com.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Frequency of Use Page:

Frequency of Use:

The iGrow Hair Rejuvenation System should be used every other day (do not use for one full day between sessions). It is not recommended for use on consecutive days. The total time of each session is from **20-25 minutes, depending on the option selected.** Exceeding the recommended times or frequency **will not** increase the effect of the iGrow.

Contraindications Page:

Contraindications:

- **THE iGROW HAIR REJUVENATION SYSTEM HAS NO KNOWN CONTRAINDICATIONS OR SIDE EFFECTS OTHER THAN SENSITIVITY TO THIS SPECIFIC WAVELENGHT OF LIGHT (655nms).**
- **IF YOU ARE USING TREATMENTS LIKE ROGAINE® OR PROPECIA® AND HAVE QUESTIONS, PLEASE CONSULT YOUR PHYSICIAN.**

This unit is intended for men 18 years and older. It should not be used by women or children

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Warnings Page:

Warnings:

TO REDUCE THE RISK OF ELECTRICAL SHOCK, THAT MAY CAUSE INJURY OR DEATH:

- Always attach the power supply to the unit first, and then connect the plug into outlet.
- Do not place or store the unit where it can fall or be pulled into a tub or sink.
- Do not place or drop into water or other liquid.
- Do not use while bathing.
- If the unit accidentally falls into water or other liquid, unplug it from the electrical outlet immediately. DO NOT REACH INTO OR TOUCH THE WATER.
- Avoid getting the iGrow Hair Rejuvenation System wet. This may result in electric shock.
- Use only the power supply provided with the iGrow.
- Never operate the iGrow if it has a damaged cord or plug. If it is not working properly or it has been dropped or damaged or submerged in water, return the product to Apira Science, Inc. for examination or repair.
- Keep the cord away from heated surfaces. Contacting a heated surface with the cord or a plug can cause the product to malfunction and produce an electrical shock.
- Always unplug the iGrow Hair Rejuvenation System from the power outlet immediately following use.
- Only use the iGrow Hair Rejuvenation System according to the instructions provided. Any other use is not recommended.

WARNING - VIEWING THE LASER OUTPUT WITH CERTAIN OPTICAL INSTRUMENTS (FOR EXAMPLE, EYE LOUPES, MAGNIFIERS AND MICROSCOPES) WITHIN THE DISTANCE OF 100MM MAY POSE AN EYE HAZARD.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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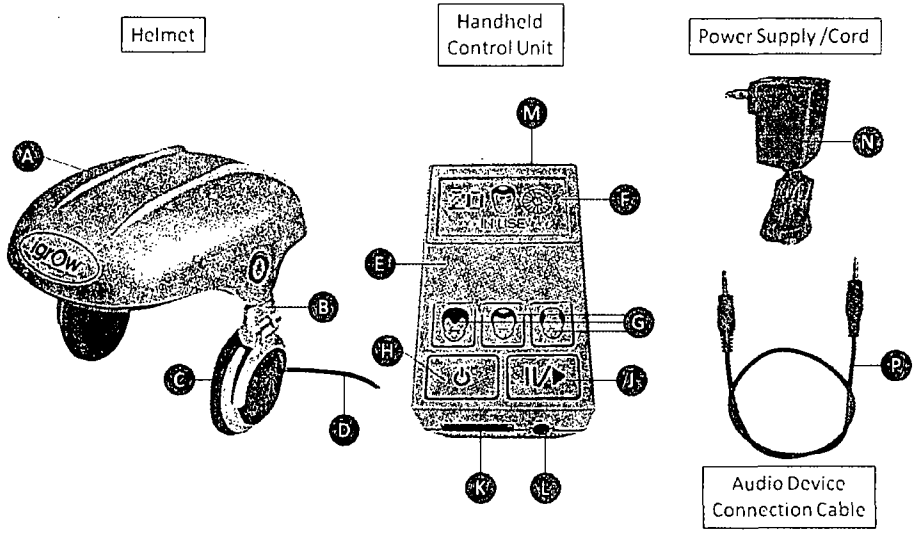
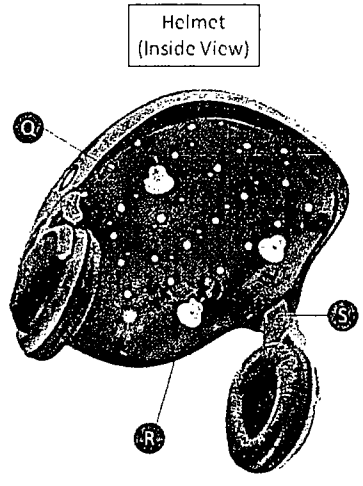
Components List Page:

Diagram 1:
iGrow Hair Rejuvenation System Components:





A - Helmet
B - Retractable Folding Hinge
C - Built-in Headphones
D - Cable for Handheld Control Unit
E - Handheld Control Unit
F - LCD Display
G - Program Buttons
H - Power (On/Off) Button
J - Pause/Start Button
K - Port for Connection to Headset
L - Port for 3.5mm Audio Cord
M - Port for Power Supply
N - Power Supply
P - Audio Device Connector Cable
Q - Laser and LED Array
R - Adjustment Spacing Columns
S - Electronic Protection Sensor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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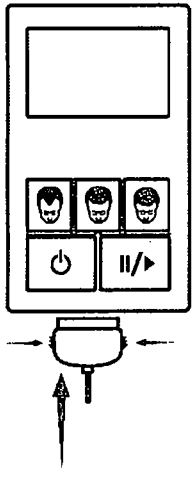
Instructions for Use Page(s):

The iGrow Hair Rejuvenation System should be used every other day with one day between sessions. It is not recommended for use on consecutive days. The total time of each session is from 20-25 minutes, depending on the option selected. This duration is automatically controlled by the system. Exceeding the recommended times or frequency will not increase the effect of the iGrow.

The letter references in this section refer to the part list shown previously in Diagram 1.

Step 1
Unpack the components of the **iGrow Hair Rejuvenation System** and make sure all the parts are present according to Diagram 1. If there are parts missing contact customer service at **1-866-982-7472** or support@igrowlaser.com.

Step2
Insert the iGrow cable connector (D) from the iGrow Helmet into the port (K) on the Handheld Control Unit (E). Hold the spring clips on the side of the connector while inserting the cable into the Handheld Control Unit (E). The embossed arrow on the connector head should face upwards while viewing the top of the Handheld Control Unit (E). Do not force the connector into the port.



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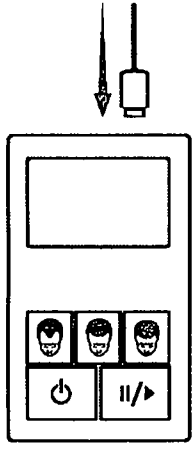
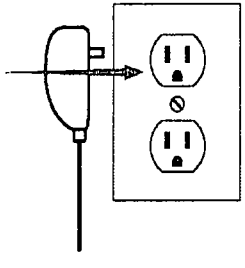
Step 3
Plug the smaller end of power supply (N) into the connection port (M) at the top of the Handheld Control Unit (E). This connector is designed to be inserted with the wider side of the connector facing the top of the Handheld Control Unit (E). Do not force the connector into the port.



Step 4
Plug the pronged end of the power supply (N) into a convenient electrical outlet.



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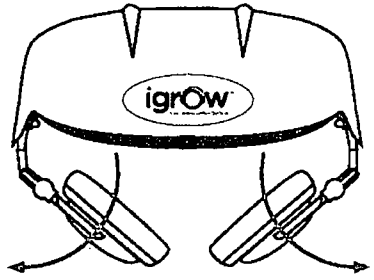
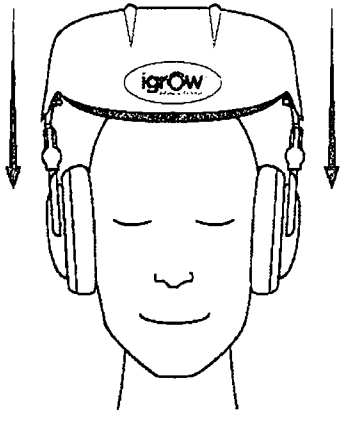
Step 5
Fold out the retractable head phones (C) of the Helmet (A) using the retractable folding hinge (B) and place the iGrow Helmet (A) onto the head.



Step 6
Place the iGrow Helmet (A) comfortably on top of the head with the headphones (C) securely covering the ears. The iGrow logo should be facing forward and be visible above the forehead if viewed in a mirror. In addition, each headphone is marked left and right using letters to indicate such.



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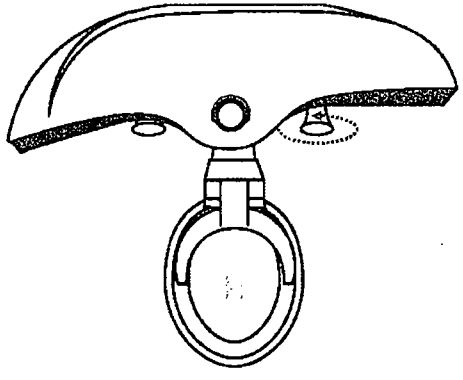
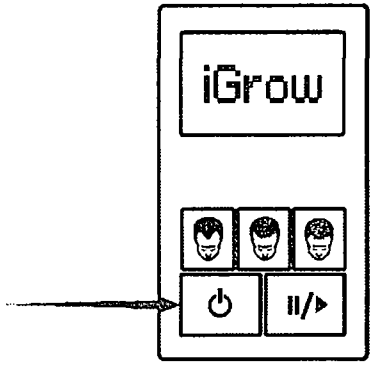
Step 7

The iGrow Helmet (A) **must** sit flat on the head. It should not be tilted to the front or the back of the head or from side to side. If needed, adjust the spacing columns (R) of the Helmet (A) so it sits securely on the head. Each of the spacing columns (R) can be adjusted by **grasping the column base** with your fingers and turning each column counterclockwise (longer) or clockwise (shorter) until a comfortable fit is achieved.



Step 8

Push the Power button (H) located on the iGrow Handheld Control Unit (E) to turn the unit **ON.** The word **"iGrow"** will appear on the LCD display (F) of the Handheld Control Unit (E).



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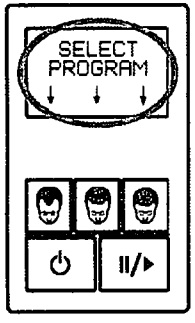
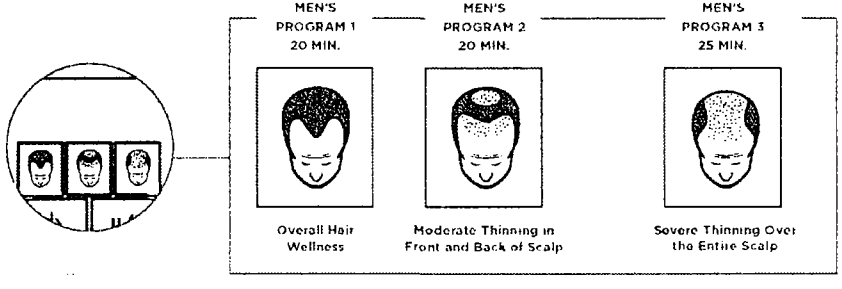
Step 9

"Select Program" will appear on the LCD display (F) of the Handheld Control Unit (E).



Step 10

Select a pre-programmed option from the Handheld Control Unit (E) by pressing one of the buttons (G) that best matches your hair restoration needs.



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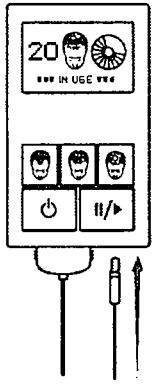
Step 11

Optionally, plug one end of the supplied audio connector cable (P) into the earphone jack of an iPod, MP3 or other compatible audio source. Plug the other end of the connector into the receptor (L) on the iGrow Handheld Control Unit (E). If not connected to an audio source, the headphones (C) allow for normal hearing.



Step 12

If the iGrow Helmet (A) is removed from the head before the completion of a session, the Electronic Protection Sensor (S) will stop the session and the LEDs (Q) will turn off. The iGrow Handheld Control Unit (E) will automatically pause operation and the LCD Display (F) will indicate that the unit has been paused. To continue the session, place the iGrow Helmet (A) back on the head and press the pause/start button (J).

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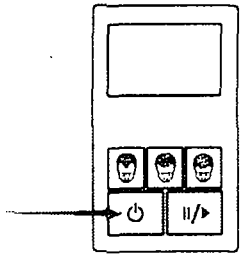
Step 13

When the session is finished, **"Session Complete"** will appear on LCD Display (F).

Step 14

Push the Power button (H) located on the iGrow Handheld Control Unit (E) to turn the unit **OFF**. The LCD Display will go blank indicating the power is off.

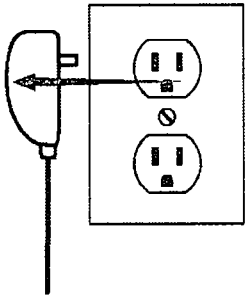


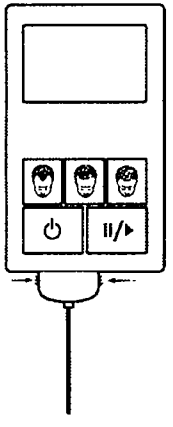
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Step 15

Unplug the power supply from the electric outlet, disconnect all connector cables from the Handheld Control Unit (E), and remove the Helmet (A). Depress the springs on the connector end of the cable (D) for the Handheld Control Unit (E) when removing. Pulling this cable our without depressing these springs can cause permanent damage to the unit. Properly store your iGrow System in accordance with the recommendations listed in the warning section above.





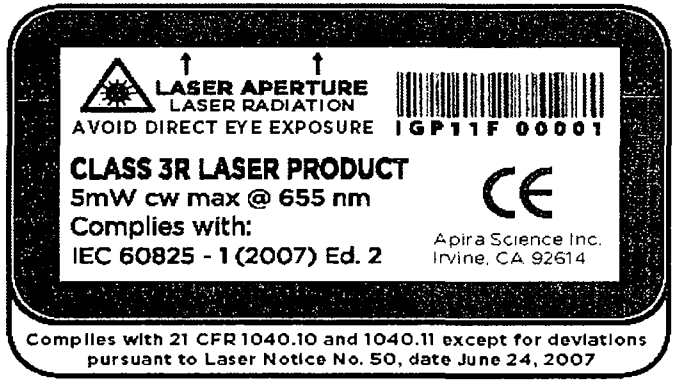
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Safety Label Page:

Safety Label

The following laser safety label can be found on the inner canopy of the Helmet (A).



Wavelength: 655 +/- 5nm

Visible Red Light - Class 3R

The iGrow Laser Hair Rejuvenation System complies with IEC 60825 - 1 Ed. 2 (2007) standards

The lasers of the iGrow are classified as "Class 3R" and are deemed completely safe for medical use. The iGrow gives off no heat or harmful radiation, causes no pain and does not require the use of drugs or topicals.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Power Supply Specifications Page:

POWER SUPPLY SPECIFICATIONS

Output from the transformer: 5V
Audio Jack: 3.5mm

The power supply for the iGrow Hair Rejuvenation System has been designed for use in the United States and Internationally. The power supply will adapt to 110 Volt/60 cycles (US) or 240 volt/50 cycles. If the power outlets in your country use plugs different than the type supplied with the iGrow, it will be necessary to obtain an appropriate country specific plug adaptor (these are not supplied with this unit).

Maintenance Instructions Page:

The iGrow is designed to provide years of trouble free operation. If it is necessary to clean the unit surfaces please follow these instructions. Note: the iGrow has no parts that can be serviced by the user. If service is required, contact Apira Science, Inc.

ALWAYS UNPLUG THE iGROW HAIR REJUVENATION SYSTEM FROM THE POWER OUTLET BEFORE CLEANING IT.

DO NOT use Acetone or any other solvents on any part of the iGrow. Acetone and other solvents will damage the unit and void the warranty.

To clean the iGrow, gently apply a soft microfiber cloth to the surfaces. Extra care must be taken to clean the underside of the unit around the light sources. Do not use excessive pressure or force as this may damage the iGrow unit.

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Section 17

Marketing Clearances for the Hairmax Lasercomb and the MEP-90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2007

Lexington International, LLC
% King & Spaulding, LLP
Mr. Edward M. Basile
Senior Partner
1700 Pennsylvania Avenue, Northwest
Washington, District of Columbia 20006-4706

Re: K060305
Trade/Device Name: HairMax LaserComb
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating for Hair Growth
Regulatory Class: II
Product Code: OAP
Dated: September 29, 2006
Received: September 29, 2006

Dear Mr. Basile:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

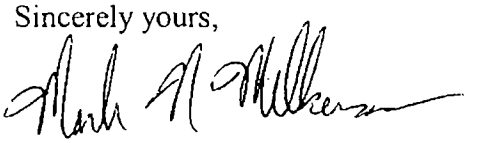
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Indications for Use

510(k) Number (if known): K060305

Device Name: HairMax LaserComb

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.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K06 0305

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
WDC_IMANAGE-805437 v1-11743.189001

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

K060305

510(k) SUMMARY

Lexington International, LLC LaserComb

JAN 18 2007

Submitter's Contact Information

Name: David Michaels, Managing Director

Address: Lexington International, LLC
2650 North Military Trail, Suite 360
Boca Raton, FL 33431

Telephone: (561) 417-0200
Facsimile: (561) 892-0747

Name of Device and Name/Address of Sponsor

Trade Name: HairMax LaserComb

Sponsor Contact Information: David Michaels
Lexington International, LLC
2650 North Military Trail, Suite 360
Boca Raton, FL 33431

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	Manufacturer
Robi Combi	Epilady 2000, LLC
DermaLight Psoracomb	Solitec GMBH
Quantum WARP 10 Light Delivery System	Quantum Devices, Inc.
Lumiphase-R	Opusmed Inc.
TerraQuant MQ2000 Laser Therapy Device	Escada International, Inc.
MLT R694 Ruby Laser System	Medical Laser Technologies Ltd.
L600 Hair Removal	A&M Technology
Violet Ray Device	Manufacturer unknown
Vacuum Cap	Evans
Raydo and Wonder Brush	Dr. Scott

Date Prepared: September 27, 2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
WDC_IMANAGE-805439 v1-11743.189001

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

K060305

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 23 2010

Midwest RF, LLC
% Mr. Helmut Keidl
President
1050 Walnut Ridge Drive
Hartland, Wisconsin 53029

Re: K091496
Trade/Device Name: MEP-90 Hair Growth Stimulation System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 15, 2010
Received: January 20, 2010

Dear Mr. Keidl:

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

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,

For Peter Pinnamaneni
Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

INDICATIONS FOR USE

510(k) Number: K091496

Device Name: MEP-90 Hair Growth Stimulation System

Indications For Use: The MEP-90 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:

> The treatment of androgenic alopecia in females by promoting hair growth of females with androgenetic alopecia who have Ludwig and Savin Hair Loss Scale classifications of I to II and who have been determined to have a Fitzpatrick Skin Typing of I to IV.

Prescription Use: ✓ **AND/OR** **Over The Counter Use:** _____
(Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091496

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Section 18

Corporate Marketing Materials for Hairmax Lasercomb and MEP-90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

RESULTS

Users of the HairMax will notice some or all of the following benefits:

- ✓ New hair growth of dormant follicles
- ✓ A substantial decrease in hair fallout
- ✓ Increased speed of hair growth
- ✓ Increased manageability of the hair
- ✓ Decrease in dandruff and/or scalp itch
- ✓ Overall better quality and condition of the hair

HAIRMAX®

Additional Information

For further information on the HairMax visit

www.hairmax.com

This Web site contains comprehensive details on the product and also allows visitors to make a secure online purchase or ask questions directly to the manufacturer via the user forum.

How to Order

The HairMax LaserComb is available for purchase by accessing the web site: www.hairmax.com

or by calling:

1 800 9 REGROW (1 800 973 4769)

Sales associates are available 24 hours a day, 7 days a week.

Lexington Intl., LLC
777 Yamato Road, Suite 105
Boca Raton, FL 33431
T. 561.417.0200 F. 561.892.0747

LEX 7001-05 06/11

QUESTIONS AND ANSWERS

Q: Who is the best candidate for the HairMax®?

A: HairMax can be used by men and women (Lux 9 model for women) with thinning hair or pattern baldness caused by a hereditary condition. Physicians use a system known as the Norwood Hamilton Classification (men) and the Ludwig (Savin) Scale (women) to describe the degree of hair loss. Your physician can discuss with you whether the HairMax is appropriate for treating your condition.

Q: How often do I need to use the HairMax® ?

A: It is recommended to use the HairMax 3 times per week with at least a day between each treatment. Depending on the model, the total treatment time varies from 8 to 15 minutes.

Q: Can the HairMax® be used with other medications?

A: Yes, there are no contraindications against using HairMax with other medicines. You should, however, discuss this with your physician and determine which methods of treatment best suit your individual needs.

Q: Will results improve when the HairMax is used more frequently than 3 times a week for 15 minutes?

A: It has been found that three times a week is the optimal amount of usage needed to generate maximum results. Using the HairMax more than three times per week has not shown any additional benefits of treatment.

Q: How long before results are seen from use of the HairMax?

A: User experience varies, but in general, improvement will start to be seen after 12 weeks of treatment. However, since hair grows slowly, we recommend that the HairMax be used for at least 20 weeks before judging results.

QUESTIONS AND ANSWERS

continued...

Q: When is the best time to use the HairMax?

A: The HairMax is best used after showering. It can be used on a wet or dry scalp, but should be used before applying any topicals, gels or other hair products.

Q: Will additional hair fall out when using the HairMax?

A: Some users experience an initial increase in telogen fallout after starting treatment. This is a good sign and indicates that healthy (terminal) hair is growing up from the scalp and will soon take the place of the former telogen hair.

Q. What is the difference between the 3 models?

A: The laser energy delivered by each of the devices is the same. The only difference is in the treatment time needed at each session. The more lasers the device has the less time is needed.

Q: How often do I have to charge the HairMax?

A: The HairMax is equipped with a built-in lithium ion battery and once fully charged (in 2-3 hours) it can be used for approximately 10 hours of continuous use. When the battery requires charging, the HairMax will turn off. It is recommended that you always return the HairMax to the charging cradle after each use to keep it fully charged.

Q: Does the laser power of the HairMax diminish if the battery is not fully charged?

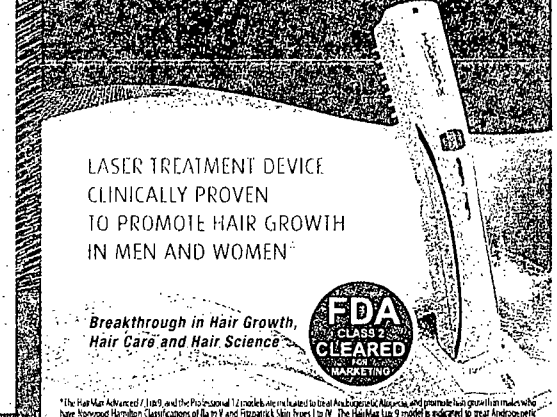
A: If the laser power diminishes it is due to the low battery and the device will automatically power off. It is recommended that you carry the power cord with you if you are away from the charging cradle location for an extended period of time.

Q: How do I use the HairMax to treat my hair loss?

A: Place the HairMax flat on your scalp so that both rows of the teeth are touching your scalp. Start by moving the HairMax against the way your hair grows from front to back. Following that, move the HairMax from side to side. Repeat these passes for the total recommended treatment time of your device.

HAIRMAX®

PATIENT INFORMATION



LASER TREATMENT DEVICE
CLINICALLY PROVEN
TO PROMOTE HAIR GROWTH
IN MEN AND WOMEN*

Breakthrough in Hair Growth, Hair Care and Hair Science

FDA CLASS 2 CLEARED FOR MARKETING

*The HairMax Advanced 7, Lux 9, and the Professional 12 models are indicated to treat Androgenetic Alopecia, and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV. The HairMax Lux 9 model is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-1, I-2, I-3, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

Have questions?
Contact a
Sales Representative.

Call toll Free: 1-800-9-REGROW
1-800-973-4769
International: 1-561-417-0200

HairMax
Healthy Hair Regimen

Formulated for use with the HairMax LaserComb.
Learn More

Medical Advisors
We now proudly introduce our Medical Advisory Board, a further extension of our dedication to quality.
Read more

HairMax LaserComb Research

- HairMax success measured in number of people whose lives are enriched
- Field experience with the HairMax supports clinical study that device is highly efficacious
- Field research demonstrates 93% user satisfaction with the HairMax
- 2010 – key HairMax clinical study demonstrated efficacy in females
- 2010 – *clinical studies demonstrated efficacy in males with 3 new models*
- 2005 Key clinical and scientific studies with the HairMax demonstrated efficacy in males
- 2003 - first HairMax IRB study showed 84.2% success in hair growth and over 45% hair count increase
- 2002 - HairMax independent study demonstrated 78.9% increase in tensile strength and 93.5% increase in hair counts.

Lexington International, LLC is a leader in hair growth, hair care and hair science. Our primary objective is to help those suffering from androgenetic alopecia. Our goal is to provide an effective treatment that is affordable, easy to use and provides noticeable results without adverse side effects. Lexington bases its success on the number of people whose lives are enriched. We truly care about conducting our business ethically and appropriately.

Our clinical Studies correlate directly with our field experience demonstrating that the HairMax LaserComb is a highly efficacious treatment for certain cases of androgenetic alopecia. The science behind Laser PhotoTherapy and PhotoBioStimulation is very practical. Usage of the HairMax LaserComb to date has been substantial. We have satisfied users in over 150 countries and have gained strong support from leading hair luminaries. Our extensive feedback overwhelmingly shows a positive user experience. Along with strong clinical data we believe that a key success criteria is user experiences - this is an area where we believe the HairMax LaserComb excels. Our field research demonstrates that 93% of HairMax users are satisfied with the results of their HairMax LaserComb.

Along with forging ahead with an active clinical agenda, we are committed to aiding clinical hair research and adding to scientific literature.

Below are descriptions of studies conducted by Lexington which have helped to further knowledge on the treatment of hair loss. These studies have helped to validate the efficacy of the HairMax LaserComb in hair growth and have made the device an important part of the overall treatment for hair loss.

2010 - Key Clinical Study in Support of 510(k) Submission to the FDA and Subsequent Clearance to Market in 2011

A double-blind, device controlled clinical study was performed at leading research centers to qualify and quantify the efficacies of the HairMax as a medical device for use in treating androgenetic alopecia (hair loss) in females. Patients, with ages ranging from 25 to 60, were included in a six month evaluation period. Hair counts were measured at baseline, at 16 weeks and at the final visit at 26 weeks. Also, subjects in the HairMax group reported significantly greater increase in hair thickness and density.

At the end of the six-month period, 100% of the subjects in the study showed successful new hair growth with an average hair count increase for all patients of over 20%. These numbers medically and scientifically significant.

2009 - Evaluation of the Activity of Laser Doses on Ex-Vivo Hair Growth

The results of a study comparing the elongation of hair in a special medium from various laser wavelengths compared to those not exposed to laser energy was conducted. The results after 10 days daily exposure to the various wave lengths showed that they all elongated hair vs. the control hairs that showed no elongation.

2005 - Key Clinical Study in Support of 510(k) Submission to the FDA and Subsequent Clearance to Market in 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9808; Released by CDRH on 09-29-2015

The results of the key clinical study performed with the HairMax LaserComb which led to FDA clearance to market was published in the May 2009 Issue of Clinical Drug Investigation. The article entitled, HairMax LaserComb Phototherapy Device in the Treatment of Male Androgenetic Alopecia, is indexed as Clin Drug Invest 2009: 29 (5): 283-292 in most of the biomedical databases such as MEDLINE, EMBASE/Excerpta Medica, etc.

Please click here to read about this study

2003 - First IRB Clinical Study

Clinical studies were performed under an Independent Review Board protocol at a leading research center to qualify and quantify the efficacies of the HairMax as a medical device for use in treating androgenetic alopecia (hair loss). Patients, with ages ranging from 26 to 76, were included in a six month evaluation period. Study subjects were required to have thinning hair in the scalp area and have active hair loss at the time of entrance into the study. Analysis was conducted at two locations on the scalp, in the temporal and vertex areas.

Before use of the LaserComb began, each area was clipped and a high-resolution photograph of the location was made. These photographs were loaded into an imaging system that identified each hair shaft. After magnification, a standard hair count was carried out and the number was recorded for comparison later in the study. Following the initial marking and hair count, each patient was provided with a HairMax LaserComb®. They were instructed to use it twice a week for the prescribed time of approximately 10 minutes, covering the entire scalp twice with each treatment.

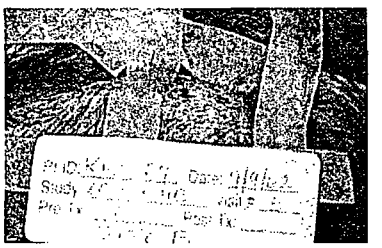


Image from our 2003 Clinical Study showing the methodologies used

Each month, the patient would return to the clinic to have the study areas clipped, new photographs taken and new hair counts recorded.

At the end of the six-month period, 97.4% of the patients in the study showed benefits from using the HairMax LaserComb®. Additionally, 84.2% of study participants showed successful new hair growth with an average hair count increase for all patients of over 45%. These numbers are significantly better than any other product tested to date for hair re-growth.

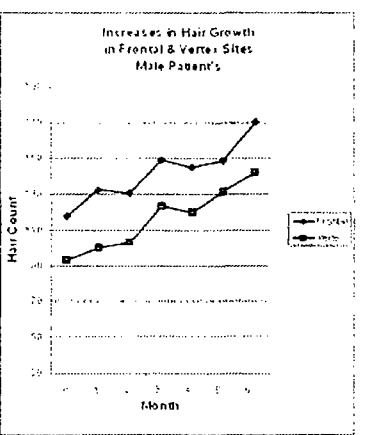
Response criteria

Benefit: Benefit to treatment was defined as lack of hair loss, or > 0% change from baseline in hair count.

Hair Growth: Success in hair growth was defined as an increase in hair count of > 11% from baseline.

Statistical Significance

All p-values for the study were statistically significant. The p-value (or the probability that a variate would assume a value greater than or equal to the observed value) for this study's endpoint (<0.0001) indicates that the results of this study would have a very high probability of being valid across the general population. In other words, the general population of men and women suffering from hair loss would, in all probability, see the same hair count increases as seen by the patients in this study.



Charts showing the increases in hair growth in the frontal & vertex sites for Males

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2002 - Study

The second clinical evaluation in 2002 was independently conducted, without any funding by Lexington, published by Dr. Michael Markou in the peer reviewed medical journal 'International Journal of Cosmetic Surgery and Aesthetic Dermatology'. This evaluation on 35 individuals demonstrated an average of 78.9% increase in hair tensile strength and 93.5% increase in average hair counts.
Click here for the Study Report (PDF)

Initial Studies in Australia

Initial Research and development of the HairMax LaserComb® began in the 1980s in Sydney Australia where CEO Henry Pearl was a pioneer in the use of laser phototherapy in a clinical setting to activate hair growth. The results were dramatic with men experiencing substantial improvements in hair growth, regrowth and overall quality of hair.

The first clinical evaluation conducted in 1993 used a laser-based combination of laser irradiation, laser acupuncture and high frequency electrotherapy, with the proprietary name 'cell wave therapy'. The evaluation was performed over a 15-month period to ascertain its efficacy in delaying or reversing male androgenetic alopecia. The trial was divided into 3 phases, each of 5 months duration.

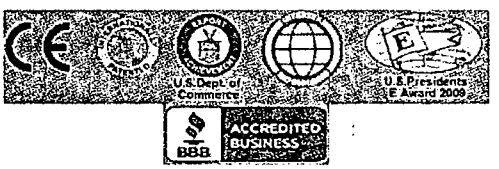
1st PHASE: 80% of the actively treated group showed a 27% mean increase in hair density at the end of the first phase...whilst the control group had a loss of 4.5%. This is a statistically significant trend to increase hair density, with a p value of 0.02.

2nd PHASE: This increase in hair density was maintained by the actively treated group.

3rd PHASE: After the actively treated group ceased therapy they had a significant loss of hair density with a p value of 0.001.

Customer Satisfaction is of Primary Importance
- ✔ Clinically Proven to Promote Hair Growth*
- ✔ Greater than 90% User Satisfaction Reported
- ✔ Patented and Manufactured in the USA
- ✔ ISO Quality Assured
- ✔ Proud Members of the Better Business Bureau

*The HairMax Advanced 7, Lux 9, and the Professional 12 models are 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.



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Have questions?
Contact a
Sales Representative.

Call toll Free: 1-800-9-REGROW
1-800-973-4769
International: 1-561-417-0200

Key Clinical Studies on the HairMax LaserComb

- Since 2001, 7 clinical studies have been conducted with 460 subjects
- Key clinical study on the HairMax published in peer review journal
- Results of study used to support HairMax LaserComb FDA 510(k) submission
- HairMax treated hair loss and promoted hair growth in 93% of users
- No serious side effects ever reported from treatment with the HairMax
- Benefits of using the HairMax: decrease in hair fallout, increased speed of hair growth, more manageability of hair and overall better quality and condition of hair

Since 2001, there have been 7 clinical studies conducted on the HairMax. In 2010, 2 of the studies were conducted on males and 2 were conducted in females.

Clinical Results

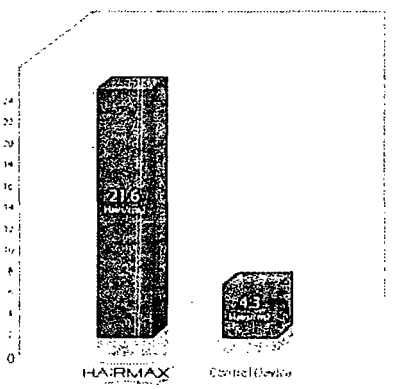
Subjects in the HairMax LaserComb® laser hair treatment group had:

- Significantly greater increase in mean terminal hair count than subjects in the control group.
- Significantly better subjective assessments of thickness and fullness of hair than subjects in the control group.
- No subject experienced a serious adverse event from the laser hair loss treatment.
- Adverse event profiles were similar between the HairMax and control groups.

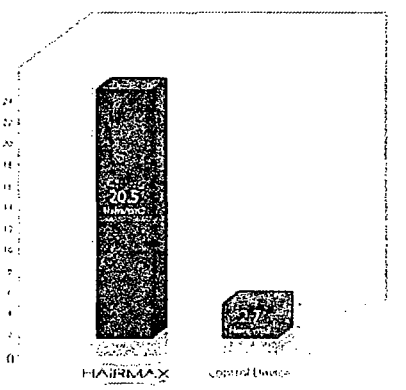
HairMax
Healthy Hair Regimen

Formulated for use with the HairMax LaserComb
Learn More

Mean Terminal Hair Count Changes From Baseline in **MALES**
26 Weeks, Last Observation Carried Forward
(Outliers Excluded)



Mean Terminal Hair Count Changes From Baseline in **FEMALES**
26 Weeks, Observed Hair Count



Medical Advisors
We now proudly introduce our Medical Advisory Board, a further extension of our dedication to quality.
Read more

Users of the HairMax LaserComb® laser hair growth treatment* received some or all of the following subjective benefits:

- A substantial decrease in hair fallout.
- Some users experienced an initial increase in telogen fallout after starting treatment, but after this period, new anagen growth was observed.
- Increased speed of hair growth.
- More manageability of the hair.
- Overall better quality and condition of hair.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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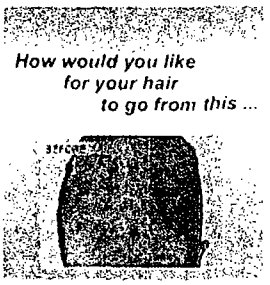
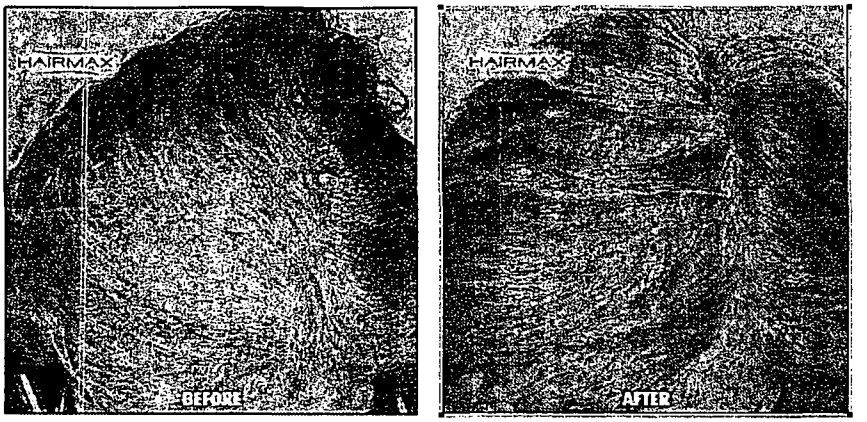
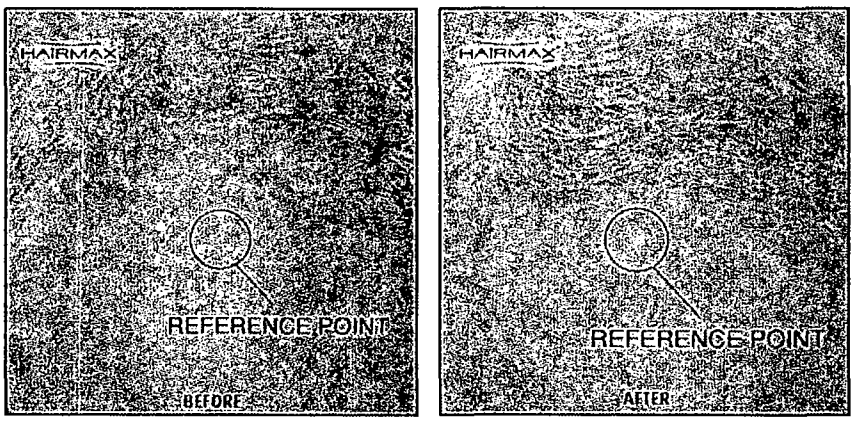


Qualified subjects had global images recorded at each visit using a stereotactic device



Substantial increase in hair density Overall improvement of hair quality



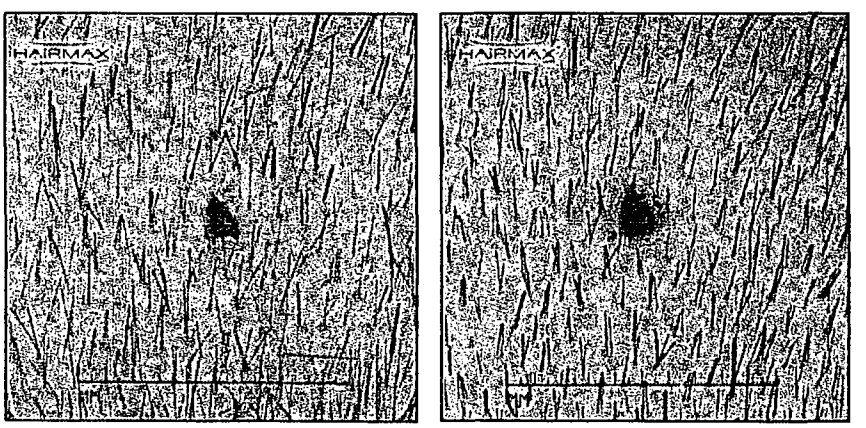
Filling in of hairline. Substantial Increase in hair density.
Overall Improvement of Hair Quality

The photos shown above are of actual HairMax LaserComb users, but are not intended to represent results everyone who uses the device will necessarily experience. Qualified subjects had global images recorded at each visit using a stereotactic device.

Non-Vellus Hair Density Macro Images

At baseline, a circle approximately 1 inch in diameter, positioned in the transition zone of the scalp, was identified as the site for hair clipping and tattooing. Within this site was the target area for the hair density evaluation during the laser hair growth treatment. Subjects were evaluated at baseline, week 8, week 16 and week 26. Digital images captured by FUJI S2 were taken of the target site within the clipped area following the site preparation. A 19 inch monitor was used for blinded evaluation.

The image below corresponds with the un-retouched Macro images shown and demonstrate a 20% increase in hair growth density.



Actual clinical study photo above shows 29 hair/cm increase after 26 weeks of laser hair growth treatment.

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Study Objectives

- ✓ promotion of hair growth through changes in hair count
- ✓ cessation of hair loss
- ✓ overall scalp health
- ✓ safety

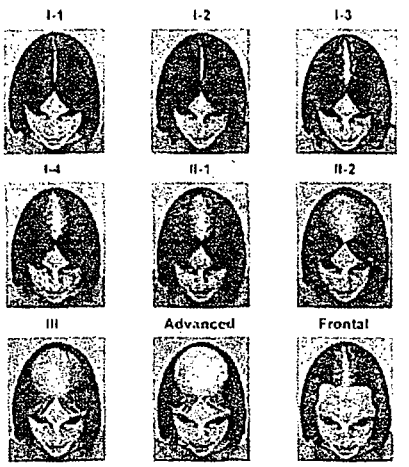
Study Design

All studies were designed as a multi-centered, double- blinded, randomized control-device trials conducted at eight sites in the United States. Subjects were instructed to use the laser hair growth treatment device three times per week on non-consecutive days, 10-15 minutes per treatment for a total of 26 weeks. Hair density measurements were performed at baseline immediately prior to randomization and again at 16 and 26 weeks. Additional clinical visits were scheduled to monitor the laser hair loss treatment progress and overall hair growth.

Subject Population and Demographics

The study population included males and females between the ages of 25 and 60 years with a diagnosis of Androgenetic Alopecia who had been experiencing active hair loss within the last 12 months. The inclusion criteria for males required a Norwood- Hamilton classification of IIa to V and Fitzpatrick skin types I to IV. The inclusion criteria for females required a Ludwig (Savin) classification of I-4, II-1, II-2, or frontal. All subjects were randomized for laser hair loss treatment analysis. A biostatistician calculated the study to be of a proper size to gauge statistically significant results of hair growth and hair density.

Ludwig Savin Chart
Female Classification System of Hair Loss



Norwood-Hamilton
Male Classification System of Hair Loss

Lexington limited the skin types for the subjects in the studies to Fitzpatrick I to IV to facilitate the hair counting process. It is difficult to count dark hairs on dark skin and therefore the darker Fitzpatrick skin types (V and VI) were not included in the study.

Methods

After diagnosing the scalp for Androgenetic Alopecia and exclusion of other dermatological conditions, subjects were randomized with either our active laser hair loss treatment device, or sham device. Subjects were then photographed for global evaluation and the target site of the scalp was identified and tattooed for baseline density. Subjects were then provided a device without usage instructions from the investigator per the protocol for OTC use. Subjects returned to the clinic at 8 and 16 weeks with a final visit at week 26 for clinical evaluation of hair counts and hair growth.

The results of the key clinical study performed with the HairMax LaserComb which led to FDA clearance to market was published in the May 2009 Issue of Clinical Drug Investigation. The article entitled, HairMax LaserComb Phototherapy Device in the Treatment of Male Androgenetic Alopecia, is indexed as **Clin Drug Invest 2009: 29 (5): 283-292** in most of the biomedical databases such as MEDLINE, EMBASE/Excerpta Medica, etc.
Please click here to read an abstract of this study

Prior Studies

Please click here to read about our prior clinical studies with the HairMax LaserComb®.

Customer Satisfaction is of Primary Importance
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- ✓ Greater than 90% User Satisfaction Reported

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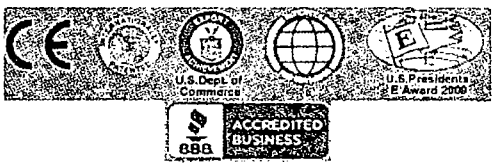

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INTRODUCTION

Some say it is the hair that makes the man or the woman; it's been called our crowning glory and defines our style, framing our personal presentation. For many people, losing their hair is a frustrating experience.

Thanks to the HairMax LaserComb®, there is now well founded hope for those suffering from hair loss and thinning hair.

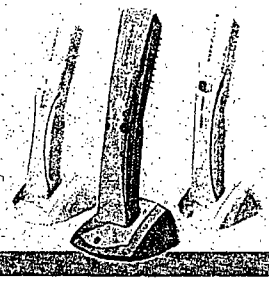
Lexington International, LLC began developmental work on Laser PhotoTherapy over 20 years ago in Australia. Since then, the company has been at the forefront of this emerging technology. In 2001, the HairMax was introduced to the market and, from its inception, over 92% HairMax users are satisfied with their results.

In 2007, based on a multi-center clinical study, the HairMax received Clearance for marketing by the U.S. FDA for the treatment of androgenetic alopecia and the promotion of hair growth in males. In 2011, based on multi-center clinical studies, the HairMax received clearance for marketing by the FDA for the treatment of androgenetic alopecia and promote hair growth in females*.

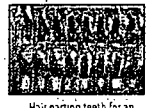
Since 2001, there have been a total of seven clinical studies completed with 460 subjects and all of the studies have demonstrated the efficacy and safety of the HairMax.

The hand-held HairMax is available without a prescription and is a one time cost that delivers long term benefits. It is portable, easy to use, and requires only three treatments per week. HairMax is even described as "therapeutic" or "soothing" by many of its users.

Now available in 3 different models and marketed in 155 countries, HairMax is fast becoming the standard for effective hair loss treatment.



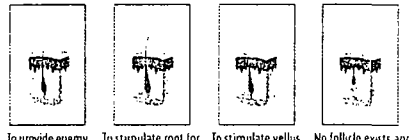
HOW THE HAIRMAX WORKS



Hair parting teeth for an unobstructed path to the hair follicle.

The HairMax® works via the principle of PhotoBio Stimulation, a process by which laser energy is delivered to the hair follicle. Laser PhotoTherapy stimulates growth factors within the hair follicle. Some users report stabilization of hair fallout at the onset of treatment followed by subsequent faster and thicker new hair growth. This points to the fact that the HairMax effectively targets the hair follicle at the cellular level and in some way both speeds up the hair growth process while at the same time inducing the growth of a thicker (or terminal) hair where a thin, dying hair may have been in place previously.

TREATMENT OBJECTIVES



To provide energy for healthy growth. | To stimulate root for new growth of healthy hair. | To stimulate vellus follicle to encourage the transformation back to healthy hair. | No follicle exists and this stage of the condition is beyond revitalization.

Clinical evidence demonstrates reversed miniaturization, increase number of hairs per follicular unit and prolongs anagen phase.

INDICATIONS FOR USE

*The HairMax Advanced 7, Lux9, and the Professional 12 models are indicated to treat Androgenetic Alopecia, and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and Fitzpatrick Skin Types I to IV.

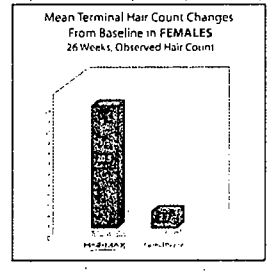
The HairMax Lux 9 model is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-1, II-1, II-2, or frontal patterns of hair loss and Fitzpatrick Skin Types I to IV.*

Your healthcare provider will discuss with you whether the HairMax is appropriate for treating your condition.

STUDIES DEMONSTRATING HAIRMAX EFFECTIVENESS IN WOMEN

In 2010, a double-blind clinical trial was conducted in females, aged 25 to 60 years of age with androgenetic alopecia at a number of research site across the country. These trials were also conducted under strict GCP (Good Clinical Guidelines) and were approved by an IRB (Independent Review Board) and overseen by a CRO (Contract Research Organization).

The subjects were randomized to HairMax® Lux 9 or a control device. Subjects used the HairMax for 26 weeks and were evaluated for change in hair count over baseline measurement. Below is a chart of the results.



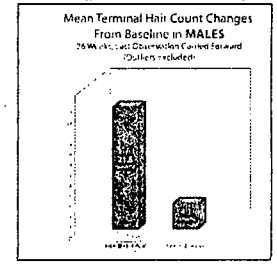
As can be seen, those subjects using the HairMax experienced an average of 20.5 hairs per cm² (squared centimeter) vs. 2.7 hairs per cm² for the control device at the end of the study at 26 weeks. This hair count is an average, and some subjects using the HairMax experienced over 40 hairs increase per cm² over their baseline. While subjects in the HairMax group experienced hair growth at 16 weeks, hair growth increased dramatically at the end of the study at 26 weeks. Most importantly, 100% of all subjects using the HairMax experienced hair growth at 26 weeks and no serious side effects were reported. Subjects also reported seeing an increase in thickness and fullness of their hair.

The results of this study was a key part of the 510(k) submission and subsequent Clearance for marketing granted in 2011 for the treatment of female pattern hair loss.*

STUDIES DEMONSTRATING HAIRMAX EFFECTIVENESS IN MEN

In 2011, two double-blind clinical trials were conducted in males, aged 25 to 60 years of age with androgenetic alopecia at a number of research site across the country. These trials were conducted under strict GCP (Good Clinical Guidelines) and were approved by an IRB (Independent Review Board) and overseen by a CRO (Contract Research Organization).

The subjects were randomized to either the HairMax Advanced 7, the HairMax Lux 9, the HairMax Professional 12 or a control device. Subjects used the HairMax for 26 weeks and were evaluated for change in hair count over baseline measurement. Below is a chart of the results.



As can be seen, those subjects using the HairMax experienced an average of 21.6 hairs per cm² (squared centimeter) vs. 4.3 hairs per cm² for the control device at the end of the study at 26 weeks. This hair count is an average, and some subjects on the HairMax experienced over 50 hairs increase per centimeter² over their baseline. Most importantly, over 93% of all subjects using the HairMax experienced hair growth at 26 weeks and no serious side effects were reported. Subjects also reported seeing an increase in thickness and fullness of their hair.

In 2006, a clinical trial of the HairMax compared to a sham device was submitted to the FDA as part of a 510(k) filing. The study was designed to assess the promotion of hair growth, changes in hair density and safety. This study showed that the HairMax was effective and safe in the treatment of hereditary hair loss in males* and was a key factor in the granting of FDA clearance for marketing in 2007.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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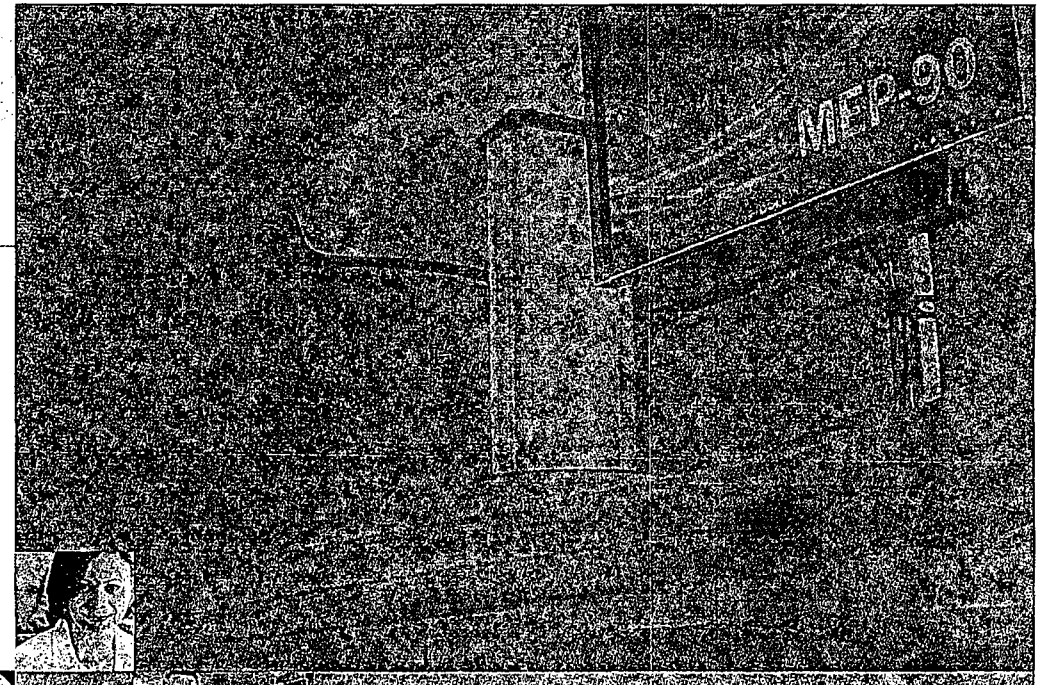
As Easy on Your Practice as It is on Your Patients

In addition to the MEP-90's sleek looks and sophisticated technology, we've designed this advanced medical laser system to be easy to operate and maintain – and we'll provide installation and training.

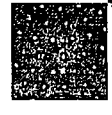
- The MEP-90 is 100% computer controlled, with an easy-to-use touch screen graphical interface.
- Safe-use sensors immediately discontinue laser therapy in the event of patient non-compliance.
- PC platform allows for future software upgrades, and new feature capabilities.
- Therapy arm and cabinet are configurable right and left to fit any clinic setting. The MEP-90 is designed to allow each facility to utilize its existing patient treatment furniture and chairs for added flexibility and patient comfort.
- Midwest RF will provide each facility with one day of installation and training. Training will cover safety and operation of medical laser devices and, specifically, use of the MEP-90.
- Extended Service Warranty packages are available for up to three additional years.



The MEP-90 meets the same FDA laser safety code as lasers employed in Lasik surgery, laser pain therapy, and other medical laser procedures.

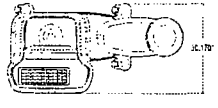
Breakthrough, Clinically-Proven Therapy for Androgenic Alopecia in Women

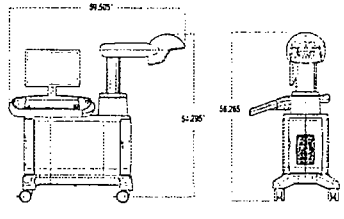
MEP-90



Learn More About This Exciting New Treatment Alternative

For more information about the MEP-90 and what it can mean to your practice – as well as the countless women searching for an effective treatment for this distressing medical condition – visit www.midwestrf.com or call 262-367-6925.





midwest rf

1050 Walnut Ridge Drive
Hartland, WI 53029

Tel (262) 367-6925
Fax (262) 367-7684

www.MidwestRF.com

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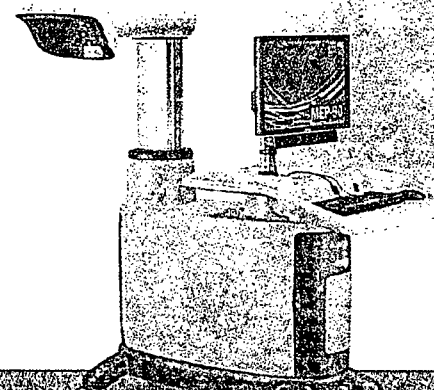
The First FDA Approved Medical Device Proven to Stimulate Hair Growth in Women

Now there is a clinically proven, non-drug, non-invasive medical treatment option for the estimated 27 million women suffering from androgenic alopecia (pattern baldness). The breakthrough MEP-90 Hair Growth Stimulation System employs laser biostimulation, and is proven in clinical studies to promote measurable new hair growth.

- The only FDA-cleared device specifically for female hair-loss patients, the MEP-90 is a Class II medical device that meets the same FDA laser safety code as lasers employed in Lasik surgery, laser pain therapy, and other medical laser procedures.



How the MEP-90 Works

This medically prescribed choice utilizes a flexible treatment schedule of Low Level Laser Therapy (LLLT) treatments to the total scalp area. Unlike medical lasers designed to cut, burn or vaporize hair follicles, these 'cold lasers' are designed to stimulate hair growth in a comfortable treatment procedure.

- The MEP-90 is a contoured laser with 82 low-level laser light diodes completely covering the scalp with measured light stimulation. During the treatments, the laser light energy stimulates blood flow and cellular metabolism in the scalp, using a scientific principal called photobiostimulation.
- Clinical studies suggest that twice-weekly 20-minute treatments over the course of six months produces remarkable results in the vast majority of patients

Powerful, Proven Results

Androgenic alopecia has a profound emotional effect on women. The MEP-90 offers proven results. In a three-phased clinical study conducted by Dr. Grant Koher of the Koher Center for Hair Restoration, subjects received 36 scheduled 20-minute treatments over a period of 18 weeks. The MEP-90 demonstrated clinical efficacy in stimulating significant measurable hair growth:

- 97% demonstrated an increased hair count of 20%
- 89% demonstrated an increased hair count of 30%
- 57% demonstrated an increased hair count of 50%

You now have a treatment option specifically for female patients with androgenic alopecia.

It is believed that increased tissue oxygenation plays a significant role in the proven effectiveness of laser hair therapy.

- The MEP-90 is available to licensed physicians only and offers an FDA-approved treatment for a devastating condition for which few medical options were previously available.*

(*While there has been a proliferation of 'cosmetic' lasers marketed to salons, spas and hair loss clinics, they are not indicated for medical use by the FDA and are coming under increasing scrutiny by federal and state regulatory agencies.)

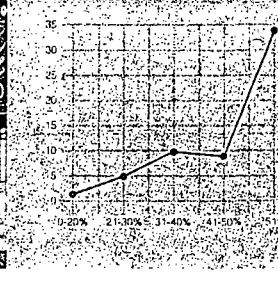
MEP-90 Hair Growth Stimulation System

Device Listing Number:	2135565
510(k) Number:	K091496
Regulatory Class:	Class II
Product Code:	OAP
Regulation Number:	21 CFR §890.5500
Regulation Name:	Infrared Lamp
Usage:	Prescription
Laser Classification:	Class 3r
Measured Wavelength (l):	650nm (±8.8%)
Measured Power Output:	53mwcm

The MEP-90 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:

Medically prescribed use for the treatment of androgenic alopecia in females: The treatment of androgenic alopecia in females by promoting hair growth of females with androgenic alopecia who have Ladwig and Savin Hair Loss Scale classifications of I to II and who have been determined to have a Fitzpatrick Skin Typing of I to IV.

18-Week Hair Count Distribution



After the 36th treatment, 97% of the subject population demonstrated an increased hair count of 20%. A total of 89% of all subjects demonstrated an increased hair count of 30%, with 57% demonstrating an increased hair count of 50%.

midwest rf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 19

Standards Data Report for 510(k)s

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120, Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Classification of laser equipment in accordance with IEC 60825-1 Edition 1.2, 2001-08

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#21CFR1040.10	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

TANDARD TITLE
Conformance with IEC 60825-1 AM.2 and IEC 60601-2-22 - Laser Notice 50

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21CFR 1040.10(b)	Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21CFR 1040.10(c)(1)	Classification	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21CFR 1040.10(d)	Accessible Emission Limits	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

TANDARD TITLE
Conformance with IEC 60825-1 AM.2 and IEC 60601-2-22 - Laser Notice 50

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(f)(5)	Laser Radiation Indicator	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(f)(7)	Location of Controls	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(g)	Labeling Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

TANDARD TITLE
onformance with IEC 60825-1 AM.2 and IEC 60601-2-22 - Laser Notice 50

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(e)	Tests for Determination of Compliance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(f)(1)	Protective Housing	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

ECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.10(h)(1)	User Information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
Conformance with IEC 60825-1 AM.2 and IEC 60601-2-22 - Laser Notice 50

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040.11(a)	Medical Laser Products	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Conformance with IEC 60601-1 and IEC 60601-1-2

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1010	Performance Standards for Electronic Products	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
21 CFR 1040	Performance Standards for Light Emitting Products	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Section 20

Certification of Compliance, Clinical Trials. gov Data Bank

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2013-9608, Released by CDRH on 09-29-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Apira Science, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
September 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
2601 Main Street
Suite 530
Irvine, CA 92614

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 866-982-7472
(Fax) 949-854-9922

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

TopHat655
Laser Comb
Non-Heating Lamp
Infrared lamp

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s): NCT01437163

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Raymond R. Blanche

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Raymond R. Blanche
(Title) Project Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
NST Consulting, LLC
541 Shunpike Rd., #311
Chatham, NJ 07928

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 973-539-7444
(Fax) 973-539-7445

15. DATE OF CERTIFICATION
July 9, 2012

Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118