DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 14, 2015

HairLabs International Incorporated
Mr. James Britt
President
742 Harpeth Knoll Road
Nashville, Tennessee 37221

Re: K142824
Trade Name: LX-100 Hair Growth Stimulation System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP, NHN
Dated: September 25, 2014
Received: September 30, 2014

Dear Mr. Britt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of 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. 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,

Jennifer R. Stevenson -S

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

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	

Template Name: K1(A) – SE after 1996

Template History:

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
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)…" Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful…" Replaced incorrect semicolon with a comma.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142824

Device Name
LX-100 Hair Growth Stimulation System

Indications for Use *(Describe)*
The LX-100 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:
Adjunctive use for the treatment of androgenic alopecia in females; the LX-100 is indicated to promote 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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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

FOR FDA USE ONLY

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

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

HairLabs International Inc.

510(k) Summary

(as required per 21 CFR: §807.92)

LX-100 Hair Growth Stimulation System

I. Applicant: Hairlabs International, Incorporated
742 Harpeth Knoll Road
Nashville, TN 37221

Phone: (615)-646-9537

II. Contact Name: James Britt, President
james@hairlabs.com

III. Device Name:

Proprietary Name…….. LX-100 Hair Growth Stimulation System

Common/Usual Name…….. Light Therapy Hair System

Classification Name…….. Infrared Lamp per 21CFR 890.5500

Product Code(s)……. OAP

IV. Predicate Devices And Comparison

Predicate Device Comparative Item 501(k) Number	Hairlabs International LX-100 K142824	Midwest RF MEP-90 K091496	Theradome Inc. LH80 Pro K122950
Device Name	LX-100 Hair Growth Stimulation System	MEP-90 Hair Growth Stimulation System	Laser Helmet LH80 PRO
Manufacture	Hairlabs International, Inc.	Midwest RF, LLC	Theradome, Inc.
Establishment Registration Number	N/A	2134565	Unknown
Device Regulation Description	Infrared Lamp	Infrared Lamp	Infrared Lamp
Device Regulation Number	21CFR; §890.5500	21CFR; §890.5500	21CFR; §890.5500
Device	A device that emits	A device that emits	A device that emits

Regulation Identification/ Classification	energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers to provide topical heating.	energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers to provide topical heating.	energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers to provide topical heating.
Physical State	Light emitting stimulator	Light emitting stimulator	Light emitting stimulator
Product Nomenclature	Lamp, infrared	Lamp, infrared	Lamp, infrared
Product Code	OAP	OAP	OAP
Device Class	Class 2	Class 2	Class 2
21CFR Part 1010 Laser Classification/ Compliance	IIIa; IIIr Full Compliance	IIIa; IIIr Full Compliance	IIIa; IIIr
FDA Device Risk Classification	Non-significant (NSR)	Non-significant (NSR)	Non-significant (NSR)
Wavelength (λ)	650nm (+/-1%) 644nm to 656nm Measured	650nm (+/-1%) 644nm to 656nm Measured	678nm center wavelength Published
Output Per Diode in mw	≤4.5mW Measured	≤4.5mW Measured	≤5mW Unpublished
Treatment Area in cm2	1065.10 cm2 Mathematically derived	990.80 cm2 Mathematically derived	990.80 cm2 Mathematically derived
Total Output for Treatment Area, Dosage mW/cm2	.3802 mW/cm2 Mathematically Derived	.3724 mW/cm2 Mathematically Derived	.4037 mW/cm2 Mathematically Derived
Recommended Treatment Regimen	2 – 20 Minute Treatments Per Week, On Non-consecutive Days for 26 Weeks for a Total of 52 Treatments	2 – 20 Minute Treatments Per Week, On Non-consecutive Days for 18 Weeks for a Total of 36 Treatments	2 – 20 Minute Treatments Per Week, On Non-consecutive Days for 26 Weeks for a Total of 52 Treatments
Fluence, 20 Minute Treatment J/cm2	.45629 J/cm2 Mathematically derived	.44691 J/cm2 Mathematically derived	.48446 J/cm2 Mathematically Derived
Number of Lasers	90	82	80
Laser Pulse Rate	Continuous	Continuous	Continuous
Laser Pulse Duration	Continuous	Continuous	Continuous
Power	3Volts DC; 110 Volts AC converted to 24 Volts DC	3 Volts DC; 110 Volts AC converted to 24 Volts DC	Unknown proprietary

Aiming Beam	No lens; diffused beam, fixed coverage	No lens; diffused beam, fixed coverage	No lens, diffused beam, fixed coverage
Laser Beam Scattering Outside Aperture	None – Fixed angulation and required beam interruption prevent beam scattering outside of Helmet assembly	None – Fixed angulation and required beam interruption prevent beam scattering outside of Helmet assembly	None when patient is in helmet.
Output Mode	Direct Light	Direct Light	Direct Light
Sterilization	Basic cleaning, Instructions provided; No sterilization claimed, called for or possible	Basic cleaning, Instructions provided; No sterilization claimed, called for or possible	No sterilization claimed or called for in published materials
Device Type	Free standing, movable laser helmut, spherical laser helmet	Free standing, movable laser helmet, spherical laser helmet	Portable helmet only, sits on patients head, spherical laser helmet
Accessories	None; all items described are necessary for basic operation including safety keys for key lock, 10' medical grade power cord, operation manual and 2 pair laser safety glasses	None; all items described are necessary for basic operation including mouse, keyboard, monitor, safety keys for key lock, 10' medical grade power cord, operation manual and 2 pair laser safety glasses	None; all items described are necessary for basic operation including wall charger

Materials	Injection molded and painted polycarbonate and polystyrene, Molded and painted fiberglass. All paint is two part epoxy based.	Injection molded and painted polycarbonate and polystyrene, Molded and painted fiberglass. All paint is two part epoxy based.	Unkown and would be proprietary information under 18U.S.C.§1832- Assumed no issues due to issuance of 510(k)	Unknown and would be proprietary information under 18U.S.C§1832- Assumed no issues due to issuance of 510(k)
Biocompatibility	There are no new materials in use on this device that are not in routine use on other devices. The biocompatibility is comparable to any of the legally marketed devices listed as follows: Midwest RF K091496 Model MEP-90 Sunetics International K132646 Model Clinical Laser G Theradome, Inc K122950 Model LH80 PRO	Assumed no issues due to issuance of 510(k)	Assumed no issues due to issuance of 510(k)	Assumed no issues due to issuance of 510(k)

Indications of Use	LX-100 is for adjunctive use for the treatment of androgenic (androgenetic) alopecia in females and is indicated to promote hair growth of females with androgenic (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	MEP-90 is for adjunctive use for the treatment of androgenic (androgenetic) alopecia in females and is indicated to promote hair growth of females with androgenic (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	Laser Helmet LH80 PRO is an over the counter (OTC) device indicated to treat androgenic alopecia, to promote hair growth in females with female pattern hair loss (FPHL) on the Ludwig and Savin Hair Loss Scale I-II, Fitzpatrick Skin-Types I to IV
Indications of Use Source	Prescription	Prescription	Over The Counter
Indications of Use Sale and Usage Restrictions	Direction of Licensed Physician only	Direction of Licensed Physician only	Over The Counter
Indications of Use Installation	Certified on site	Certified on site	Drop shipped to user
Indications of Use Operator and User Training / Education	Factory and/or on site training at installation; Internet access for Operations Manual	Factory and/or on site training (User option) of approximately 6-8 hours at installation; Internet access for operational updates; Operation Manual; Continuing education program TBD	Operation manual
Indications of Use Operation Control and Length of Treatment	Default settings for recommended treatment protocol; Operator resets of time and dosage which is controlled by computer	Default settings for recommended treatment protocol; Operator resets of time and dosage which is controlled by computer	Single button control, button push starts one 20 minute cycle, unit turns off when cycle ends

Indications of Use Safety In Operation	Warning labels on device; key lock with on screen warning; default treatment settings; fixed maximum power output regardless of settings; constant thru beam interrupt by patient required for laser operation; warning on screen to insure operator and patient are wearing safty glasses before lasers will operate; no beam scatter outside of helmet assembly; tilting of head no ≥3/8" interrupt	Warning labels on device; key lock with on screen warning; default treatment settings; fixed maximum power output regardless of settings; constant thru beam interrupt by patient required for laser operation; warning on screen to insure operator and patient are wearing safty glasses before lasers will operate; no beam scatter outside of helmet assembly; tilting of head no ≥3/8" interrupt; head proximity safety circuitry	Unknown - proprietary

V. Indications For Use

The LX-100 is a non-heating lamp as described under the provisions of 21 CFR §890.5500 and is indicated for:
Adjunctive use for the treatment of androgenic alopecia in females; the LX-100 is indicated to promote 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

VI. Technological Characteristics

The LX-100 is a stationary low-level laser device that promotes hair growth and provides adjunctive treatment for androgenic (androgenetic) alopecia in females. The device provides automated and timed equal distribution of laser light to 100% of the scalp.
The LX-100 operation is controlled by an operating system that affords the user maximum flexibility for individual treatments. The device applies a measured very high tolerance (≤+1%) wavelength (λ) to the scalp stimulating hair growth by the proven concept of biostimulation.

Performance Data and Clinical Efficacy

The LX-100 Hair Growth Stimulation System met all of the specified acceptance criteria of the design verification and validation testing performed under design control and is found to be substantially equivalent to the currently marketed and approved predicate devices.

VII. Conclusion

The LX-100 is substantially equivalent to other pulsed therapeutic light therapy systems currently in commercial distribution. The LX-100 has the same intended use and technological and safety characteristics to the predicate devices approved for commercial distribution under 510(k) number K091496, and K122950.

It equals the clinically accepted therapeutic results standards of FDA 510(k) K091496, and K122950 previously approved light therapy systems.

The technological equivalence to the predicate devices is substantiated by the wavelength, power output and dosage generated by the LX-100. The LX-100 provides expanded treatment benefits and regimens for clinical presentations already approved by the Food and Drug Administration for the predicate device.

The LX-100 is as safe and effective as a combination of the predicate devices listed and numerous others. It has the same intended use of affecting hair growth as the hair growth predicate device (K091496, and K122950). In addition, the LX-100 has the same general indications, i.e., treating androgenic alopecia, and the same specific indication of promoting hair growth as the predicate device.

The LX-100 also has many of the same or similar technological characteristics as a combination of its predicate devices. These include multiple lasers and visible laser wavelength.