May 18, 2018

Theradome, Inc.
% Jacqueline Hauge
Regulatory Affairs Consultant
Jacqueline A. Hauge
23300 Manning Trail N
Scandia, Minnesota 55073

Re: K180460
Trade/Device Name: Theradome LH40
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 14, 2018
Received: February 20, 2018

Dear Jacqueline Hauge:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180460

Device Name
Theradome LH40 (Theragrow)

Indications for Use *(Describe)*

The Theradome LH40 (Theragrow) is an over-the-counter (OTC) therapeutic device intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2; both with Fitzpatrick Skin Types 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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I. SUBMITTER

Date Prepared: February 14, 2018

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Regulatory Consultant
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Fax: 925-374-1202

Establishment Registration# 3008295459

Sponsor Contact: Tamim Hamid, PhD, CEO
Phone: 510-714-0525

II. DEVICE

Trade Name:	Theradome LH40 (Theragrow)
Common Name:	Lamp, non-heating, for promotion of hair growth
Classification Name:	Infrared Lamp
Product Code	OAP
Regulatory Class:	Class II
Regulation Number:	21 CFR 890.5500
Panel:	General and Plastic Surgery

III. PREDICATE DEVICES

Primary:	K161046	Theradome LH40 Evo (Theradome, Inc.)
Additional:	K171775	Theradome LH80 Pro (Theradome, Inc.)
Reference:	K152473	HairMax LaserComb 41 (Lexington International, LLC.)

IV. PURPOSE OF SUBMISSION

The purpose of this Premarket Notification is to obtain FDA clearance for the expanded indications for use statement for the Theradome LH40 device to include treatment of Androgenetic Alopecia and promotion of hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss.

V. DEVICE DESCRIPTION

The Theradome LH40 (Theragrow) laser helmet is a low level laser therapy (LLLT) device containing red, visible light diode lasers operating at 678 nanometers, designed to deliver non-thermal energy to the hair follicles to promote hair growth via photobiostimulation of the scalp. The lasers are contained inside a lightweight, one-size-fits-all helmet. The Theradome LH40 device utilizes 40 laser diodes to deliver laser stimulation to the entire scalp for hands-free operation during treatment. The device is one-button operated, and has an audible timer that automatically turns the lasers off after the 20 minute treatment is complete.

VI. INDICATIONS FOR USE

The Theradome LH40 (Theragrow) is an over-the-counter (OTC) therapeutic device intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2; both with Fitzpatrick Skin Types I to IV.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Low level laser therapy (LLLT) is the principle technology for both the subject and predicate devices. At a high-level, the Theradome LH40 (Theragrow) device has the same technological characteristics as the predicate device, including:

- Number of Laser Diode
- Laser Class
- Laser Power
- Wavelength
- Laser Delivery Method
- Helmet Design
- Single Button Operation
- Audible Timer
- Treatment Time and Duration
- Materials of Construction
- Risk Profile
- Battery Operation

The fundamental scientific technology of the Theradome LH40 device was not changed as part of this submission.

Comparison of Theradome LH40 to Predicate Devices

Technological Characteristic	Theradome LH40	Theradome LH80	HairMax LaserComb 41	Theradome LH40
Regulatory Information				
Manufacturer	Theradome, Inc.	Theradome, Inc.	Lexington Int'l, LLC	Theradome, Inc.
510(k) Number	K161046	K171775	K142573	K180460
Product Code	OAP	OAP	OAP	OAP
Device Type	OTC Only	OTC Only	OTC Only	OTC Only
Technological Characteristics Comparison				
# of Coherent Light Diodes	40	80	41	40
Coherent Light Class	Class 3R	Class 3R	Class 3R	Class 3R
Wavelength (nm)	678 ($\pm$7)	678 ($\pm$7)	655 ($\pm$10)	678 ($\pm$7)
Laser Power for Classification	5mW	5mW	<5mW	5mW
Power Flux (mW/cm^2)	0.476	0.952	Not Reported	0.476
Radiant Energy per Treatment (J)	432	216	Not Reported	432
Fluence (J/cm^2)	0.52	1.03	0.0	0.52
Treatment Schedule	4 times/week	2 times/week	3-4 times/week (every other day)	4 times/week
Treatment Time	1200 sec (20 min)	1200 secs (20 min)	30 seconds at each of 6 positions on the scalp	1200 sec (20 min)
Total Treatment Time	4800 sec/week (80 min/week)	2400 sec/week (40 min/week)	720 seconds (9-12 min/week)	4800 sec/week (80 min/week)
Device Configuration				
Device Configuration	Helmet	Helmet	Band	Helmet
Device Dimensions (cm)	17.5x19.6x27.3	17.5x19.5x26.8	20x5x13	17.5x19.6x27.3
Device Weight (g)	425	425	156	425
Nominal Scalp Coverage (cm^2)	420	420	Not Reported	420

VIII. PERFORMANCE DATA

Performance testing was not required to support a substantial equivalence determination for the Theradome LH40 device. The existing performance testing; including biocompatibility, mechanical, software, and electrical and electromagnetic compatibility (EMC), are unchanged from the predicate device. Animal testing was not required to support a substantial equivalence determination for the Theradome LH40 device. Clinical testing was not required to support a substantial equivalence determination for the Theradome LH40 device.

IX. CONCLUSIONS

The Theradome LH40 device has been demonstrated to be substantially equivalent to the predicate device based on the equivalence of technological characteristics and intended use. Because there are no new or changed technological characteristics presented in this submission, the existing risk profile for the device remains unchanged. Theradome has demonstrated that the Theradome device is safe and effective for the expanded indications for use.