DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 12, 2016

Theradome, Inc
Vern Liebmam
Clinical & Regulatory Affairs Consultant
4900 Hopyard Road, Suite 100
Pleasanton, California 94588

Re: K161046
Trade/Device Name: Laser Helmet Lh40-evo
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 13, 2016
Received: April 13, 2016

Dear Mr. Vern Liebmam:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161046

Device Name
LH40 EVO

Indications for Use *(Describe)*

The Theradome Laser Helmet LH40 EVO is an over the counter (OTC) device indicated to treat androgenetic 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.

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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Section 6: Special 510(k) Summary

LH40 EVO: Special 510(k) Summary

Sponsor: Theradome, Inc.
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Contact: Vern Liebmann
Clinical & Regulatory Affairs, Theradome, Inc.

Date Summary Prepared: April 12, 2016

Device Trade Name: LH40 EVO

Common Name: Laser Helmet

Classification Name: Laser, Comb, Hair (Infrared lamp)

Product Code: OAP

Classification of Device: Class II (performance standards)

Classification Regulation: Title 21, Code of Federal Regulations, §Sec.890.5500. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

Predicate Devices: LH80 PRO (K122950)
iGrow-II Hair Growth System (K140931)
HairMax LaserComb 41 (K142573)

Performance Standards: FDA mandated performance standards for this device exist and are specified under 21 CFR, §1010 and §1040. These standards, including QSR requirements are followed by regulation. Voluntary standards such as UL, in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the LH40 EVO.

At the present time, the following applicable guidance documents are in effect for this device:

- Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (June 1995)
- Compliance Guide for Laser Products (FDA 86-8260)
- Laser Products, Conformance with IEC 60825-1, and IEC 60601-2-22; Guidance for Industry and FDA (Laser Notice 50)

Device Description:

Similar to the Theradome LH80 PRO, the iGrow-II and the HairMax LaserComb 41, the modified Theradome LH40 EVO 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 used to promote hair growth via photobiostimulation of the scalp. The lasers are contained inside a lightweight, one-size-fits-all helmet.

The LH40 EVO 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 completes.

Intended Use/Indication for Use:

The Theradome Laser Helmet LH40 EVO is an over-the-counter (OTC) device indicated to treat androgenetic 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.

Technological Characteristics:

The modifications to the LH80 PRO since its previous clearance in K122950 do not alter the safety or efficacy of the device. The predicate device contains 80 laser diodes. The modified LH40 EVO utilizes the same laser diodes and helmet design. The difference in the LH40 EVO versus the LH80 PRO is the number of laser diodes. The LH40 EVO contains 40 laser diodes and the LH80 PRO contains 80 laser diodes. An adjustment in the number of treatments per week (4 times per week for the LH40 EVO versus 2 times per week for the LH80 PRO) compensates for the different number of laser diodes. The modified device is an economical version of the current LH80 PRO. The outer helmet shell has been streamlined to provide a smaller profile.

Nonclinical Performance Data:

Performance Characteristics
Testing to IEC 60601-1 and 60601-1-2 confirm the device's safety and electrical compatibility.

Testing to IEC 60825-1 certifies the laser system to classification 3R, same as predicate devices.

The charger conforms to IEC 61959.

Nonclinical Testing
Design and development of the LH40 EVO followed ANSI/AAMI/ISO 14971:2007/(R)

2010 Risk Management: Medical devices – Application of risk management to medical devices.

Theradome performed a Risk Analysis to evaluate the implications of the design changes to the LH80 PRO. It was determined there was no significant change to risk and no new risks were identified with respect to the modifications to the LH40 EVO. All residual risks were found to be acceptable. It was concluded the modified design could be tested in the laboratory and no animal or new clinical data was required to show safety, efficacy or substantial equivalence to the currently cleared model.

Based on the Risk Analysis and modifications to the device, verification activities were conducted for the LH40 EVO, including the same methods and tests using the same applied acceptance criteria as the previous LH80 PRO. All the testing met acceptance criteria.

Substantial Equivalence:

The LH40 EVO is as safe and effective as the predicate device, the LH80 PRO, as well as the iGrow-II Hair Growth System (K140931) and HairMax LaserComb 41 (K142573).

The modified device has the same intended use of affecting hair growth as the predicate devices, as well as the same indications (i.e., treating androgenetic alopecia) and the same specific indication of promoting hair growth in females with female pattern hair loss (FPHL) on the Ludwig-Savin Hair Loss Scale I-II and Fitzpatrick Skin-Types I to IV (the iGROW-II is also cleared by FDA to treat males with androgenetic alopecia that fall into Norwood Hamilton classifications IIA to V). Safety profiles are the same: a total laser module output within the limitation of a Class 3R laser (per IEC 60825-1), using low-level, low-hazard laser light therapy (LLLT) with a visible red laser and the same individual laser output (≤5mW).

The LH40 EVO has the same technological characteristics as the device cleared in K122950, including its laser class, laser power, wavelength, laser delivery method, helmet design, single-button operation and audible timer. The reduction in the number of laser diodes does not change the safety or effectiveness profiles.

The modified LH40 EVO device is also similar technologically to the HairMax Laser Comb 41 and the Apria iGrow-II Hair Growth System with fewer diodes (40 laser diodes versus 41 laser diodes and 51 laser diodes/LEDS, respectively) and a similar weekly treatment regimen (3-4 times per week) provides evidence of devices with reduced delivered energy doses and similar weekly treatment regimens cleared by the FDA in the category of OAP.

Conclusion:

The modified LH40 EVO has the following similarities to the current LH80 PRO:

- the same indications for use
- the same individual laser diode output
- the same basic helmet design
- the same operating principle and technology
- the same single-button user interface
- the same audible timer function

The LH40 EVO is offered as a lower-cost alternative. Dosage per treatment is reduced, however, the weekly dosage remains the same as the LH80 PRO. The reduced energy delivered dose per treatment is comparable to the other cleared predicate devices. The difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile.

Therefore, the modified LH40 EVO can be found substantially equivalent to the LH80 PRO cleared in K122950 and the predicate HairMax Laser Comb 41 and the Apria iGrow-II Hair Growth System.