January 9, 2018

Theradome Inc.
Tamim Hamid
President and CEO
4900 Hopyard Rd, Ste 100
Pleasanton, California 94588

Re: K171775
Trade/Device Name: Theradome LH80 PRO
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 6, 2017
Received: December 11, 2017

Dear Tamim Hamid:

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)*
K171775

Device Name
Theradome LH80 PRO

Indications for Use *(Describe)*
The Theradome LH80 PRO 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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5.0 Traditional 510(k) Summary

Date Prepared: Thursday, January 4, 2018

Submitter's Contact Information:

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Name of Device and Name / Address of Sponsor:

Theradome LH80 PRO
Theradome Inc.
4900 Hopyard Road, Suite 100
Pleasanton, CA 94588
Telephone: 510-714-0525
Fax: 925-374-1202
Establishment Registration# 274120

Sponsor Contact Information:

Tamim Hamid, PhD
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Fax: 925-374-1202
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Device Name and Classification

Product/Trade Name: Theradome LH80 PRO
Common or Usual Name: Theradome LH80 PRO
Classification Name: Infrared lamp per 21 CFR 890.5500
Product Code: OAP (Coherent light, Comb, Hair)
Regulation Number: 21 CFR 890.5500
Panel: General and Plastic Surgery
Class: II

Predicate Devices:

Device Trade Name Manufacturer 510(k)

Predicate	510(k) Number	Device Name	Manufacturer
Primary	K122950	Theradome LH80 PRO	Theradome Inc.
Reference	K163170	Capillus82	Capillus LLC
Additional	K162782	iHelmet	Slinph Technologies Co., Ltd

Device Description Summary

The Theradome LH80 PRO for men and women is a low level coherent light therapy (LLLT) device utilised to promote hair growth. The coherent lights are contained inside a lightweight, one-size fits all helmet. The Theradome LH80 PRO uses 80 coherent light diodes in the helmet to deliver coherent light stimulation to the entire scalp for hands-free operation during treatment. An audible timer automatically turns the coherent lights off after the 20 minutes treatment is completed. This coherent light helmet is not constructed to be a safety helmet.

Intended Use / Indications for Use

The Theradome LH80 PRO 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.

Technological Characteristics

The Theradome LH80 PRO coherent light Helmet is a low level coherent light therapy (LLLT) device used to promote hair growth. The coherent lights are contained inside a lightweight one-size-fits-all helmet. The Theradome LH80 PRO utilizes 80 coherent light diodes to deliver coherent light 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 coherent lights off after the 20 minute treatment completes.

Performance Data

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the devices. The Theradome LH80 PRO conforms to the standard IEC-60825-2007-03. This 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]. This report validates for the Theradome LH80 PRO the coherent light class of 3R which establishes the AEL (accessible emission limits) as 5 milliwatts maximum. The data presented in this submission is restricted to self-selection and usability to include comprehension of user instructions, warnings, and precautions.

Brief Description of NonClinical Testing

As part of establishing substantial equivalence between LH80 PRO, iHelmet, and Capillus82 devices within the LH80 PRO (K171775) 510(k) submission, the technological characteristics, such as, fluence, irradiance, treatment time, number of diodes, etc. are compared within the subject and predicate devices.

Brief Description of Clinical Testing

Not applicable.

Substantial Equivalence

Theradome LH80 PRO utilizes the same fundamental technology and comparable technological parameters as the predicates. Please see table below.

Theradome LH80 PRO	Theradome LH80 PRO – Females only	Capillus82	iHelmet
K171775	K122950	K163170	K162782
LLLT Device Type	LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use/OTC	Prescription Use/OTC	Prescription Use/OTC	Prescription Use/OTC
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia
Contains coherent light diodes- Class 3R	Contains coherent light diodes- Class 3R	Contains coherent light diodes- Class 3R	Contains coherent light diodes- Class 3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
678nm	678nm	650nm	650nm
Marketing clearance for Males and Females	Marketing clearance for Females	Marketing clearance for Males and Females	Marketing clearance for Males and Females
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free
Features – One button operation, audible timer, status LED	Features – One button operation, audible timer, status LED	Features – One button operation, audible timer, status LED	Features – One button operation, audible timer, status LED
Treatment time- 20 minutes	Treatment time- 20 minutes	Treatment time- 30 minutes	Treatment time- 20 minutes
Irradiance = same	Irradiance = same	Irradiance = comparable	Irradiance = comparable
Fluence = same	Fluence = same	Fluence = comparable	Fluence = comparable
80 coherent light diodes	80 coherent light diodes	82 Coherent light diodes	200 Coherent light diodes
OAP Classification	OAP Classification	OAP Classification	OAP Classification
Classification Name - Infrared Lamp	Classification Name - Infrared Lamp	Classification Name - Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name -Lamp, Non-Heating	Common Usage Name -Lamp, Non-Heating	Common Usage Name -Lamp, Non-Heating	Common Usage Name -Lamp, Non-Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV
Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)
Device Class II	Device Class II	Device Class II	Device Class II

Conclusion

Based on the comparable indications for use and technological characteristics the subject device is substantially equivalent to the predicates.