MAR - 2 2012

K113097

Section 5 510(k) Summary

This 510k summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Manufacturer

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Official Correspondents

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Date of Submission: October 3, 2011

Device Name and Classification

Product Name:	LH80 PRO Laser Helmet Infrared lamp per 21 CFR 890.5500
Product Code:	OAP
Regulation Number:	21 CFR 890.5500
Panel:	General and Plastic Surgery
Class:	II
Substantial Equivalence claimed to:	RF Midwest LLC MEP-90 Hair Growth Stimulation System (K091496)

Device Description

The Theradome Laser Helmet LH80 PRO is a low level laser therapy (LLLT) device used to promote hair growth via photobiostimulation. The lasers are contained inside a lightweight, one-size fits all helmet. The LH80 PRO utilizes laser diodes in the helmet 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

The Theradome Laser Helmet LH80 PRO is intended to treat androgenic alopecia by promoting hair growth.

Indications for Use

The Theradome Laser Helmet LH80 PRO is a prescription use therapeutic device indicated to promote hair growth in females, with androgenic alopecia, having Ludwig and Savin Hair Loss Scale classification I-II and Fitzpatrick Skin-Types I to IV.

Technological Characteristics

The LH80 PRO delivers visible red low-level laser radiant energy to the scalp. The LH80 PRO utilizes laser diodes to deliver laser stimulation to the entire scalp for hands-free operation during treatment.

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 device.

Nonclinical Testing

Performance testing was conducted to confirm compliance to design specifications; all functions were verified to operate as designed.

Substantial Equivalence

Theradome wishes to use the following device as predicate:

RF Midwest LLC MEP-90 Hair Growth Stimulation System (K091496)

The LH80 PRO has the same intended use as the predicate device: treat androgenic alopecia by promoting hair growth.

The LH80 PRO has the same indications for use as the predicate device: prescription use device to promote hair growth in females, with androgenic alopecia, having Ludwig and Savin Hair Loss Scale classification I-II and Fitzpatrick Skin-Types I to IV.

The MEP-90 and the LH80 PRO both deliver treatment to the entire scalp for hands-free operation during treatment, and have the same treatment schedule.

For those reasons, the Theradome Laser Helmet LH80 PRO satisfies FDA's substantial equivalence with respect to both intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Theradome, Inc.
% Mr. Larry Petersen
Regulatory Affairs
1001 Bear Island Road, Suite 136
Summerville, South Carolina 29483

MAR - 2 2012

Re: K113097
Trade/Device Name: Theradome Laser Helmet LH80 PRO
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: NHN, OAP
Dated: February 12, 2012
Received: March 1, 2012

Dear Mr. Petersen:

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

Enclosure

K113097

Section 4 Indications for Use Statement

Device Name: Theradome Laser Helmet LH80 PRO

Indications for Use:

The Theradome Laser Helmet LH80 PRO is a prescription use therapeutic device indicated to promote hair growth in females, with androgenic alopecia, having Ludwig and Savin Hair Loss Scale classification I-II and Fitzpatrick Skin-Types I to IV.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKN

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113097