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

March 31, 2015

Home Skinovations Ltd.
% Ms. Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as Street, Suite 102
Kfar Saba 4442520
Israel

Re: K150175
Trade/Device Name: HeatLux Pro I
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: March 1, 2015
Received: March 6, 2015

Dear Ms. Stein:

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" (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 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 -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

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)*

K150175

Device Name
HeatLux Pro I

Indications for Use *(Describe)*

HeatLux Pro I is over the counter hand held device intended to emit energy in the visible and near IR spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and temporary relaxation of muscles.

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.

K150175

Special 510(k) Summary

K150175

510(K) SUMMARY

HEATLUX PRO I DEVICE

510(k) Number K150175

Applicant Name:

Company Name: Home Skinovations Ltd.
Address: Tavor Building, POB 533
Yokneam Iillit 2069206 Israel
Tel: +972(4)9097440
Fax: +972(4)9097471
E-mail: ahava@asteinrac.com

Contact Person:

Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: January 22, 2015

Trade Name: HeatLux Pro I device

Classification Name: CFR Classification section 890.5500; (Product code ILY)

Classification: Class II Medical Device

Predicate Device:

The HeatLux Pro I device is substantially equivalent to the previously cleared, HeatLux 1 device, also manufactured by Home Skinovations Ltd.

Device	Manufacturer	510(k) No.
HeatLux 1	Home Skinovations Ltd.	K120582

Device Description:

The HeatLux Pro I device is a hand held device, using low power light spectrum, array of 24 LEDs, at wavelength of 630±10nm, combined with four metal heating plates (temperature stabilized to 41^0c). The HeatLux Pro I device consists of an applicator and an AC/DC power adaptor. The applicator is a hand held unit used for treatment, as the treatment surface at the applicator tip comes in direct contact with the skin.

Device Specifications:

Maximal heating plates output power: 12W
Maximal optical power density: 10mWatts/cm^2
Package dimensions: 22cm x 22cm x 14cm
Weight: 250gr
Main Line Frequency (nominal): 50-60 Hz
Input Voltage (nominal): 100-240 VAC

Intended Use/Indication for Use:

The HeatLux Pro I device is over the counter hand held device intended to emit energy in the visible and near IR spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local and blood circulation, and temporary relaxation of muscles.

Performance Standards:

The HeatLux Pro I device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, (Third Edition, 2005 / 2006), Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, (Third Edition, 2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-2-57, (First Edition, 2011), IEC 60601-2-57 (2011), Medical Electrical Equipment - Part 2-57: Particular Requirements for The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use.

Non-Clinical (Bench) Performance Data:

A set of bench tests were performed to evaluate the thermal profile and temperature stability of the HeatLux Pro I device and to compare them to the thermal profile and temperature stability of the HeatLux 1 device.

The results of the bench tests demonstrated that the HeatLux Pro I device has the same thermal profile and temperature stability properties as those reported for the predicate device.

Pre-Clinical (Animal Study) Performance Data:
Not Applicable

Clinical Performance Data:
Not Applicable

Substantial Equivalence:
The indications for use and technological characteristics of the HeatLux Pro I device are substantially equivalent to the indications for use and technological characteristics of the HeatLux 1 device.
The design and components in the HeatLux Pro I device, including the wall adaptor and the applicator are similar to the design and components found in the predicate HeatLux 1 device. The battery was replaced with the direct adaptor charger for longer operation time and in order to increase the device life time. The differences do not negatively affect the safety or efficacy of the device as supported by the results of the performance tests. The performance specifications of the HeatLux Pro I device are substantially equivalent to those in the HeatLux 1 device. The safety features and compliance with safety standards in the HeatLux Pro I device are similar to the safety features and compliance with safety standards found in the HeatLux 1 device. Patient contact materials were partly modified and tested for biocompatibility. Any differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new HeatLux Pro I device underwent performance testing, including software validation testing and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 and bench tests. These performance tests demonstrated that the differences in the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the HeatLux Pro I device is substantially equivalent to the predicate HeatLux 1 device, cleared under 510(k) K120582.

Conclusions:
Based on the performance testing and comparison to predicate device, the HeatLux Pro I device is substantially equivalent to the HeatLux 1 predicate device for the above-mentioned Intended Use/Indication for Use.