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

July 29, 2016

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

Re: K152087
Trade/Device Name: Heatlux Pro II
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY, GEI
Dated: July 10, 2016
Received: July 13, 2016

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" (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,

Christopher J. Ronk -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)*
K152087

Device Name
HeatLux Pro II Device

Indications for Use *(Describe)*
HeatLux Pro II is an over the counter hand held device intended to emit energy in the visible, near IR, and RF 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 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.

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

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510(K) SUMMARY

HEATLUX PRO II DEVICE

510(k) Number K152087

Applicant Name:

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Date Prepared: July 29, 2016

Trade Name: HeatLux Pro II Device

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

Classification: Class II Medical Device

Predicate Device:

The HeatLux Pro II Device is substantially equivalent to the following predicate devices:

Device	**Manufacturer**	**510(k) No.**
VelaShape System	Syneron Ltd.	K122579
HeatLux Pro I	Home Skinovations Ltd.	K150175

Device Description:

The HeatLux Pro II Device is an over the counter, hand held device, utilizing low power light spectrum, array of 24 LEDs, at wavelength of 630±10nm and 850±50nm, RF output power (1MHz, maximal output power 24W) and electrical heating. The HeatLux Pro II Device consists of an applicator and an 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. The device applicator comprises temperature stabilizer, which constantly maintains the applicator temperature to 41^0c.

Device Specifications:

RF frequency: 1MHz

Maximal RF output power: 24W

Maximal heating plates output power: 12W

Maximal optical power density: 60mWatts/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:

HeatLux Pro II is an over the counter hand held device intended to emit energy in the visible, near IR, and RF 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 blood circulation, and temporary relaxation of muscles.

Performance Standards:

The HeatLux Pro II 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.
- IEC 60601-2-2 Edition 5.0 2009-02, Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories.

Non-Clinical (Bench) Performance Data:

A set of bench tests were performed to evaluate the thermal profile, RF depth penetration and temperature stability of the HeatLux Pro II Device.

The tests' results along with the comparison discussion to the predicate devices demonstrated that the HeatLux Pro II Device has met the system requirements. The subject device presented similar technological specifications to the presented predicate devices and therefore, is substantially equivalent to the predicate devices.

Pre-Clinical (Animal Study) Performance Data:

Not Applicable

Clinical Performance Data:

User performance (usability) study was conducted on twenty eligible device users. The study evaluated the users' ability to self-select the device, comprehend the device labeling and operate the device as intended in a safe and effective means.

The study results showed that potential device users had successfully operated the device as intended with no safety issues reported.

Substantial Equivalence:

The indications for use and technological characteristics of the HeatLux Pro II device are substantially equivalent to the indications for use and technological characteristics of the Velashape System and of the HeatLux Pro I device.

The design and components in the HeatLux Pro II device, including the wall adaptor and the applicator are similar to the design and components found in the predicate HeatLux Pro I device. Both devices utilize optical and electrical energies with the same mechanism of action. The additional technological components (i.e. the RF generator and the IR LEDs) that were disabled by the software in the HeatLux Pro I device were activated in the HeatLux Pro II device using software modifications. The activation of these technological features does not alter the functionality and performance of the subject device whereas the treatment temperature profile has unchanged as shown in the performance tests provided in section 12.

Furthermore, the HeatLux Pro II device possesses similar technological modalities as in the Velashape System predicate device. Both devices utilize Bi-polar RF energy and IR optical LEDs, for the same mechanism of action and for the same indications for use.

The safety features and compliance with safety standards in the HeatLux Pro II device are similar to the safety features and compliance with safety standards found in the HeatLux Pro I device. All patient contact materials are identical to the materials found at the HaetLux Pro I device. The HaetLux Pro I device was tested for biocompatibility

and comply with the ISO 10993-1 standard (see biocompatibility testing in section 12). The differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the modified HeatLux Pro II device underwent performance testing, including software validation testing (provided in Section 12), electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, non-laser light source equipment testing according to IEC 60601-2-57 and high frequency surgical equipment and high frequency surgical accessories testing according to IEC 60601-2-2 (provided in Section 12) and bench tests (provided in Section 12). 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 II device is substantially equivalent to the main predicate the Velashape System, cleared under 510(k) K122579 and to the reference predicate the HeatLux Pro I device, cleared under 510(k) K150175; and therefore, may be legally marketed in the USA.

Conclusions:
Based on the performance testing and comparison to predicate device, the HeatLux Pro II device is substantially equivalent to the aforementioned predicate devices for the mentioned intended use.