May 9, 2018

Home Skinovations Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520 Il

Re: K180279
Trade/Device Name: Silk'n MODEL H5003 device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: May 2, 2018
Received: May 7, 2018

Dear Amit Goren:

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,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K180279

Device Name
Silk'n MODEL H5003

Indications for Use *(Describe)*
The Silk'n Model H5003 is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.
Contraindicated use on injured or otherwise impaired muscles.
Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

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.

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510(K) SUMMARY
SILK'N MODEL H5003
510(k) Number K180279

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: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425 Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: May 09, 2018

Trade Name: Silk'n MODEL H5003

Classification Name: Powered muscle stimulator

Regulation Number: CFR Classification sections 890.5850

Product Code: NGX

Classification: Class II Medical Device

Predicate Device:

The Silk'n MODEL H5003 device is substantially equivalent to the previously cleared, Body Control System "4M", manufactured by Sport-Elec S.A.

Manufacturer	Device	510(k) No.
Sport-Elec S.A.	Body Control System "4M"	K092476

Device Description:

The Silk'n MODEL H5003 device is an over-the-counter home use EMS device intended for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. The Silk'n Model H5003 system is comprised of a treatment unit – "applicator", a belt for placing and holding the applicator and a cradle unit for charging of the applicator's battery. The device generates an electrical signal, which is required for muscle stimulation and is transferred to the muscles via the device electrodes.

The Silk'n MODEL H5003 device is easily operated by a single mode push-button, two operational buttons for selection of EMS level, and a set of light indicators informing the lay-user on the device current operation mode (i.e., EMS level treatment, standby or error), all are located on the applicator user interface board.

The Silk'n MODEL H5003 device is equipped with a safety proximity sensor, which initiates the signal only upon full contact between the electrodes and the skin, and disconnects the power in case of no contact during the device operation.

Device Specifications:

Output voltage: 30v±2.00v
Output current@500Ω: 60mA±4mA
Pulse rate: 40Hz±10Hz
Pulse width: 400µsec±50µsec

Intended Use/Indication for Use:

The Silk'n Model H5003 is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.
Contraindicated use on injured or otherwise impaired muscles.
Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Performance Standards:

The Silk'n MODEL H5003 device has been tested and complies with the following voluntary recognized standards:

- AAMI/ANSI 60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601- 1:2005, Mod).

- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

- IEC 60601-2-10 (Second Edition, 2012): Medical electrical equipment part 2: particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- IEC 60601-1-11:2010, Medical electrical equipment Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.

Non-Clinical (Bench) Performance Data:

A set of performance tests were conducted to demonstrate that the Silk'n MODEL H5003 device performs as expected under anticipated conditions of use and to verify that the device performance meets the device design requirements. The device was tested for validation of output waveform, basic unit characteristics, and output specifications.

Furthermore, the Silk'n MODEL H5003 device underwent software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, safety and essential performance of nerve and muscle stimulators testing according to IEC 60601-2-10, and medical electrical equipment testing according to IEC 60601-1-11.

The results of these tests demonstrated that all the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The below table presents a comparison of the technological characteristics of the subject device and the predicate device:

Device Characteristics	**Subject Device – Silk'n Model H5003 Device Home Skinovations Ltd.**	**Predicate Device – Body Control System "4M" Device SPORT-ELEC S. A. K092476**
Indication For Use	The Silk'n Model H5003 is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Contraindicated use on injured or otherwise impaired muscles Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	The Body Control System "4M" is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Contraindicated use on injured or otherwise impaired muscles Not intended for use in any therapy or for the treatment of any medical conditions or diseases.
Power	1 rechargeable Li-Ion battery, 3.7 V	3 batteries, 1.5V
Patient leakage current	NA for battery powered device	NA for battery powered device
Single fault condition (µA)	NA for battery powered device	NA for battery powered device
Number of output channels	1	1
Average DC current through electrodes when device is on but no pulses are being applied	0 µA	0 µA
Number of outputs modes	1	1
Regulated current or regulated voltage?	Voltage	Voltage
Software / firmware / microprocessor control?	Yes	Yes
Automatic overload trip	No	No
Automatic no load trip	No	No
Automatic shut-off	Yes	Yes

Device Characteristics	**Subject Device – Silk'n Model H5003 Device Home Skinovations Ltd.**	**Predicate Device – Body Control System "4M" Device SPORT-ELEC S. A. K092476**
User overrides control?	Yes	Yes
Indicator display – On/Off Status	Yes	Yes
Indicator display – low battery	Yes	Yes
Indicator display voltage/current level	No	No
Time range (minutes)	15	Data not available
Compliance with standards?	AAMI/ANSI 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-11	AAMI/ANSI 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-4
Compliance with 21 CFR 898	Yes	Yes
Housing material and construction	ABS	ABS
Output waveform	Symmetrical biphasic	Monophasic
Shape	Rectangular	Rectangular
Duration of primary (depolarizing) phase	0	0
Maximum output voltage (voltage, +/-10%) at 500 ohms, 2 K ohms, and 10 k ohms	32V for 500, 2K and 10Kohms	Data not available
Maximum output current (mA +/- 10%) at 500 ohms	64 mA	Data not available
Maximum output current (mA +/- 10%) at 2 K ohms	16 mA	Data not available
Maximum output current (mA +/- 10%) at 10 K ohms	3.2 mA	Data not available
Pulse width (μsec)	1000±50	Data not available
Phase duration (μsec)	400±50	Data not available
Frequency (Hz)	40±10	Data not available
Maximum current density at 500 ohms (mA/cm^2)	4.9	3

Device Characteristics	**Subject Device – Silk'n Model H5003 Device Home Skinovations Ltd.**	**Predicate Device – Body Control System "4M" Device SPORT-ELEC S. A. K092476**
Maximum average power density at 500 ohms (W/cm^2)	0.005	0.092
Symmetrical phases	Yes	No
Net charge per pulse	0 [μC]	Data not available
Maximum phase charge	25.6 [μC]	Data not available
Burst mode	a. Pulses per burst: 88 b. Bursts per second: 0.238 c. Burst duration: 2.1 [sec] d. Duty Cycle: 50%	Data not available

The Silk'n MODEL H5003 device shares many of characteristics and features with the predicate Body Control System "4M" device (cleared under K092476). Both Silk'n MODEL H5003 and Body Control System "4M" devices have a similar design, technological features, user interface and hardware components. Both devices share the basic technological principal of applying trans-cutaneous electrical muscle stimulation (EMS) through skin contact electrodes.

The Silk'n MODEL H5003 device for EMS technology has same low risk as was previously determined for the Body Control System "4M" predicate device. Both devices incorporate similar safety features, including automatic shut off of the energy source at the end of predetermined treatment time period, system abnormalities check, and safety proximity sensor. In addition to the safety features, compliance with safety standards of the Silk'n MODEL H5003 device is similar to the compliance with safety standards of the predicate device.

The only meaningful difference between the Silk'n MODEL H5003 and the Body Control System "4M" device is the electrode type. While the Body Control System "4M" utilizes Adhesive electrodes with hydrophilic gel, the Silk'n MODEL H5003 device utilizes conductive fabric electrodes. Both electrode materials are biocompatible with ISO10993-5 and ISO10993-10 requirements. A second difference between the two devices is the replacement of LCD display in the Body Control System "4M" with LED indicators in the Silk'n MODEL H5003, which raise no new safety or efficacy concerns. All other differences between the two devices are minor changes in the external design, which do not raise new safety or efficacy concerns.

Consequently, it can be concluded that the Silk'n MODEL H5003 device is substantially equivalent to its predicate Body Control System "4M" device (cleared under 510(k) K092473).