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 25, 2017

Home Skinovations Ltd.
% Mr. Amit Goren
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 44425 Israel

Re: K162784
Trade/Device Name: Silk'n HST
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS, PAY
Dated: February 15, 2017
Received: February 21, 2017

Dear Mr. 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.

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,

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)*
K162784

Device Name
Silk'n HST

Indications for Use *(Describe)*
The Silk'n HST is an over-the-counter home use device intended for non-invasive treatment of mild to moderate periorbital wrinkles for adult women who have Fitzpatrick skin types I-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.

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510(K) SUMMARY

SILK'N HST

510(k) Number K162784

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Date Prepared: March 22, 2017

Trade Name: Silk'n HST

Classification Name: 2 1 CFR Classification sections 878.4810 and 878.4420; Product codes OHS and PAY, respectively.

Classification: Class II Medical Device

Predicate Device

The Silk'n HST device is substantially equivalent to the previously cleared Silk'n FX device, also manufactured by the applicant (Home Skinovations Ltd.). In addition, the Newa™ device is used as a reference predicate.

Manufacturer	Device	510(k) No.
Home Skinovations Ltd.	Silk'n FX	K110301
EndyMed Medical Ltd.	Newa™	DEN150005

Device Description

The Silk'n HST device is designed as a hand held device, which utilizes both RF and low power light energies. The device includes RF generator, LEDs at wavelengths of 630±20nm and 850±20nm (red and IR wavelengths, respectively) and a temperature stabilizer. The Silk'n HST device consists of an applicator and an adaptor. The applicator is a handheld unit used for treatment. The treatment surface is located at the applicator tip and comes in direct contact with the skin. The applicator is equipped with an ON/OFF switch that also selects the energy level as manifested using indicators panel. The adaptor connects the applicator to the electrical outlet using its plug and the applicator socket.

Device Specifications:

Optical power density:	55 and 70mW/cm^2 (±10%)
RF frequency:	1MHz
RF power density:	10W±20%
Input Voltage (nominal):	90-264 VAC
Main Line Frequency (nominal):	47-63 Hz

Intended Use/Indication for Use

The Silk'n HST is an over-the-counter home use device intended for non-invasive treatment of mild to moderate periorbital wrinkles for adult women who have Fitzpatrick skin types I-IV.

Performance Standards

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

#	Standard	Description
1	IEC 60601-1:2005 (3rd edition) + C1:2006 + C2:2007 + Amendment 1:2012 or IEC 60601-1: 2012(reprint)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2007 (3rd &4th editions)	Medical electrical equipment; Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests
3	IEC 60601-2-2:2009 (5th edition)	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
4	IEC 60601-1-6:2010 (3rd edition) + A1:2013	Medical electrical equipment Part 1 6 General requirements for basic safety and essential performance Collateral Standard Usability
5	IEC 62366:2007 + A1:2014	Medical device – Application of Usability engineering to medical devices
6	IEC 60601-1-11:2015 (2nd edition)	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
7	IEC 60601-2-57:2011 (First edition) for use in conjunction with IEC 60601-1:2005	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

The Silk'n HST device was evaluated in a set of performance tests for its conformity with the design requirements specifications and for its optical and RF parameters and temperature profile. The testing included over-heating safety, parameter validation and power accuracy.

Furthermore, the Silk'n HST device underwent software validation testing as well as was tested and found to comply with the Electrical and mechanical safety standard (IEC 60601-1), the electromagnetic compatibility standard (IEC 60601-1-2), the non-laser light source equipment standard (IEC 60601-2-57), the medical electrical equipment standard (IEC 60601-1-11) and the particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2).

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

Animal Performance Data / Histology Data

Not Applicable

Clinical Performance Data

Safety & Effectiveness

In order to validate the safety and efficacy of the RF and optical LED combination, a clinical study was conducted at a certified clinic in the US in 30 eligible adults. The study included 21 treatment sessions every other day, over a period of 6 weeks, and 2 maintenance treatments that were performed 1 and 2 months following treatment sessions ended. The criterion for study success was a statistically significant reduction of at least 1.0 score in the average score of Fitzpatrick scale score according to at least 2 out of 3 blinded dermatologists, as measured 3 months following treatment end compared to baseline. The study results indicate that the combination of RF and optical light energies produces on average a statistically significant reduction of 1.49±0.51 Fitzpatrick scores as compared with baseline to 3-month follow-up ($p<0.001$), as determined by 3 blinded evaluators. According to the study, downgrade of at least 1 score on the Fitzpatrick Wrinkle Severity Scale score was seen in 96.7%, 90.0%, and 93.3% of the patients, as reported by the first, second and third reviewers, respectively (results are summarized in Table 1.0 below) During the study, no unexpected adverse events were detected and the treatment was associated with no to merely mild pain. Usability parameters were tested as well and indicated precise operation and safe use.

Table 1.0: Effectiveness results calculated based on completer case (N=30)	
Reviewer #1	96.67% (29/30)
Reviewer #2	90.0% (27/30)
Reviewer #3	93.33% (28/30)
≥2 agree	100% (30/30)

At the last follow-up visit, participants were asked a series of questions designed to explore the level of satisfaction regarding the device operation and treatment results. A score of 5 was defined as "Very Satisfied" while a score of 1 was "Very dissatisfied."

All study participants were (very or somewhat) satisfied with the ease of learning to use the Silk'n HST device. The data from this satisfaction questionnaire show that subjects were generally satisfied with the Silk'n HST device, where 86% of the patients (26/30) were satisfied to very satisfied with the overall device performance The vast majority of participants (29/30, 97%) indicated that there was some improvement in their wrinkle status.

Usability, Self-selection & Labeling Comprehension

In addition, a separate usability study was conducted, demonstrating that the Silk'n HST labeling materials were understandable and adequately acknowledged for the self-selection. Twenty five subjects had participated in the self-selection study with 100% success rate. Twenty of them had successfully identified themselves as potential device users and five subjects, which were deliberately contraindicated to the study inclusion criteria, had successfully self excluded from study participation.

All of the eligible 20 study subjects succeeded to perform the device related tasks, with minimal number of requests for assistance and with no errors or inefficiencies. The average time to completion of tests was 36.1 minutes. The only error that was deliberately initiated by the observer (electrical failure) was easily detected and resolved by the user. The results of the post treatment questionnaire showed that all of the patients (20/20) were comfortable with the device operation and with the ease in labeling comprehension. The labeling comprehension test indicate on a good experience of the potential users with a success rate of 100%, where all of the patients (20/20) found it easy to understand the instructions for use and perform the tasks related to treatment. These results show that the user understood the information on the device labeling, and the major communication messages that detail the safe and effective use of the device.

This study also demonstrated that the device is easy to operate by potential end-users and safe under actual use conditions.

Substantial Equivalence

The Silk'n HST device is an over-the-counter, non-invasive, non-ablative device utilizing RF and optical LED energies for the treatment of periorbital wrinkles. The main predicate device, Silk'n FX, is also a non-invasive, non-ablative device that was cleared with the indication for use of periorbital wrinkles treatment. The predicate device utilizes optical energy with the same wavelengths and other optical characteristics as the Silk'n HST device.

The design and components of the Silk'n HST device are similar to the design and components of the Silk'n FX device. The major modifications made to the Silk'n HST device are the addition of RF energy and an addition of adaptor as a substitute to the rechargeable batteries and charging cradle. The inclusion of RF energy was conducted according to a reference predicate device, Newa™, which is FDA-cleared, over-the-counter, non-invasive, non-ablative device, utilizing RF energy for the treatment of full-face wrinkles. Both the Newa™ and Silk'n HST devices apply 1MHz RF with the same output power, thus sharing the same RF-related technological parameters, which imply similar underlying mechanism of action.

All the safety features that are embedded in the Silk'n FX, namely - safety proximity sensor, temperature sensor and software protection from abnormalities are identically included in the Silk'n HST. Two additional safety features, which are related to RF energy and stem from the Newa™ device, were incorporated in the Silk'n HST. These additional safety features include a visual user interface with indicator LEDs for device status and a built-in timer that stops the RF delivery at the end of the treatment session.

All the features embedded in the Silk'n HST device are identical to those of the predicate devices. The supporting bench performance testing and clinical data indicate that the combination of both energies is safe and effective for the device intended use.

Consequently, it can be concluded that the Silk'n HST device is substantially equivalent to the main predicate Silk'n FX device, cleared under 510(k) K110301, and to the reference predicate Newa™ device, cleared under de novo DEN150005.

FaceTite - קישור לאתר ה FDA

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K162784