August 30, 2023

Silk'n Beauty Ltd.
℅ Amit Goren
Regulatory Manager
A. Stein-Regulatory Affairs Consulting Ltd.
18 Hata'as St.
Kfar Saba, 444252018
Israel

Re: K230013
Trade/Device Name: Silk'n Titan AllWays
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: January 1, 2023
Received: January 3, 2023

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tanisha L. Hithe -S

Digitally signed by Tanisha L. Hithe -S
Date: 2023.08.30 08:28:48 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230013

Device Name
Silk'n Titan AllWays

Indications for Use *(Describe)*
The Silk'n Titan AllWays is an over-the-counter home use device intended for the non-invasive treatment of mild to moderate facial 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 Titan AllWays

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

510(k) Number: K230013

Applicant Name:

Company Name: Silk'n Beauty Ltd.
Address: Alon Ha-Tavor St. 15
Caesarea 3079516, Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren, PhD
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 18 Hata'as St.
Kfar Saba 4442518 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
amit@asteinrac.com

Date Prepared: August 20, 2023

Trade Name: Silk'n Titan AllWays

Classification Name:

OHS	878.4810	Light Based OTC Wrinkle Reduction
PAY	878.4420	OTC RF Coagulation Device For Wrinkle Reduction

Classification: Class II Medical Device

Predicate Device: The Silk'n Titan Allways is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k)
Home Skinovations Ltd.	Silk'n HST	K162784

Reason for Submission:

In this submission, the Indication for Use has been expanded from treatment of periorbital wrinkles to include treatment of the entire facial area. In addition, several design and safety modifications have been implemented in the Silk'n Titan AllWays.

Indications for Use:

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

Device Description:

The Silk'n Titan AllWays is a cordless, hand-held device, utilizing RF energy and low power light spectrum. The device includes an RF generator, an array of 8 LEDs at wavelengths of 630±20nm and 850±20nm (Red and IR wavelengths respectively), and a temperature stabilizer. The Silk'n Titan AllWays consists of an applicator and an adaptor. The hand-held applicator delivers energy from the treatment surface at the applicator tip which comes in direct contact with the skin. The applicator is equipped with an ON/OFF switch (that also selects the energy level) and an indicators panel. The device can be powered by an internal rechargeable battery (cordless mode) or with the AC adaptor that connects the applicator to an electrical outlet.

Comparison of Intended Use and Technological Characteristics:

Device Characteristics		Silk'n Titan AllWays (Subject Device)	Silk'n HST Device / K162784 (Predicate Device)
Manufacturer		Silk'n Beauty Ltd.	Home Skinovations Ltd.
Product Code(s) / Class		PAY, OHS / Class II	SAME
Prescription vs. OTC		OTC	SAME
Target Population		Adult women with Fitzpatrick skin types I-IV with mild to moderate facial wrinkles	Adult women with Fitzpatrick skin types I-IV with mild to moderate periorbital wrinkles
Anatomical Sites		Entire Face	Periorbital area only
Environment Used		Home use device	SAME
RF Parameters	Max Power	10W±20%	SAME
	Frequency	1 MHz	SAME

	Waveform	Sinusoidal	SAME
Optical Parameters	Red LEDs	630±20nm / 45 mW/cm^2	630±20nm / 70 mW/cm^2
	IR LEDs	850±20nm / 57 mW/cm^2	850±20nm / 55 mW/cm^2
Energy Source	Li-ion Battery	3.7VDC / 2600 mAh	N/A
	AC Adaptor	100-240V / 50-60Hz / 0.5A 12VDC±10%	SAME
Applicator Treatment	Surface Area	4.7 cm^2	SAME
	RF Electrodes	3	SAME
	LEDs	8	SAME
Safety Features		• Safety proximity sensing • Temperature sensor • Visual user interface with indicator LEDs for device status • Timer to stop RF energy delivery after 15 minutes	SAME
Standards Met		IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 60601-1-11 IEC 60601-2-2	SAME
Biocompatibility		Materials in contact with skin are biocompatible	SAME
Sterility		Not sterile	SAME

Non-Clinical Performance Testing:

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

- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2:2014, (Fourth Edition), Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-57, (First Edition, 2011), Medical Electrical Equipment - Part 2: 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 60601-1-11:2015 (Second Edition), Medical electrical equipment - Part 1-11 – Requirements for the medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-6:2010 (Third Edition) + A1:2013, Medical Electrical Equipment - Part 1-6 General requirements for safety – Collateral Standard: Usability.
- The Silk'n Titan AllWays 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 overheating safety, power accuracy, and system parameter validation.
- The Silk'n Titan AllWays device underwent software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2, and non-laser light source equipment testing according to IEC 60601-2-57.

The results of the 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:

- 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 32 eligible adult women. The study included 2 treatment sessions a week for 10 consecutive weeks, and 2 maintenance treatments that were performed 1- and 3-months following treatment end. The study results indicate that the combination of RF and optical light energies produces a statistically significant average reduction of 1.39 Fitzpatrick scores comparing baseline to 3-month follow-up ($p < 0.001$), as determined by 3 blinded evaluators. In addition, statistical analysis revealed improvement of at least 1 score according to the Fitzpatrick Wrinkle and Elastosis scale for most patients. During the study, no unexpected adverse events were detected, and the treatment was associated with mild to no pain. Usability parameters were also tested indicating that the device is easy and safe to operate. In addition, a separate Usability Study was conducted which demonstrated that device labeling provides adequate comprehension and self-selection for potential users. The study showed as well that the device is easy to operate by potential end users and safe under actual use conditions. Finally, thermal testing was conducted in a human volunteer to show that the worst-case energy and power deposition from the device is not likely to raise skin temperature to above safe, acceptable values.

Conclusion:

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.