January 13, 2023

Home Skinovations Ltd.
℅ Amit Goren
Regulatory Manager
A. Stein Regulatory Affairs Consulting Ltd.
18 Hata'as St. Suite 21
Kfar Saba, 4442518
ISRAEL

Re: K214078
Trade/Device Name: Silk'n Toothwave
Regulation Number: 21 CFR 872.6866
Regulation Name: Radiofrequency Toothbrush
Regulatory Class: Class II
Product Code: QMJ
Dated: December 15, 2022
Received: December 15, 2022

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K214078

Device Name
Silk'n Toothwave

Indications for Use *(Describe)*
The Silk'n Toothwave is a powered radiofrequency toothbrush intended to promote good oral hygiene, including reduction of plaque, and the prevention and treatment of gingivitis.

The Silk'n Toothwave is intended for over-the-counter use.

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

THE SILK'N TOOTHWAVE

510(k) Number K214078

Applicant Name:

Company Name: Home Skinovations Ltd.
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Date Prepared: January 11, 2023

Trade Name: Silk'n Toothwave

Classification Name: 21 CFR 872.6866; (Product codes: QMJ)
Common Name: Radiofrequency Toothbrush

Classification: Class II Medical Device

Predicate Devices:

The predicate device, is the previously cleared Silk'n Toothwave device, manufactured by the applicant (Home Skinovations Ltd.), and is the exact same device as the subject device of this 510k application:

Manufacturer	Device	510(k) No.
Home Skinovations Ltd.	Silk'n Toothwave	DEN190039

Device Description:

The Silk'n Toothwave device (a.k.a Silk'n H7001 Powered Toothbrush) is a handheld, rechargeable, powered, radiofrequency toothbrush, an over-the-counter device, intended to promote good oral hygiene, including reduction of plaque and the prevention and treatment of gingivitis. The Silk'n Toothwave Device is comprised of the handheld, brush head and recharging units. The device utilizes radio frequency (RF) energy and vibration.

The Silk'n Toothwave is comprised of the handle, the brush head, and recharging unit. The brush head is designed with radiofrequency electrodes and bristles. The handheld unit contains the software, programming, and hardware necessary for the device to function. The device is operated by a push button for activation of the radiofrequency and vibration.

The Silk'n Toothwave device is operated by a single mode push-button located on the handle/hand piece user interface board and a set of light indicators informing the lay user of the device operation.

The Silk'n Toothwave device is designed as a rechargeable handheld electrical toothbrush comprised of the charging base unit and a rechargeable power handheld unit. The chargeable base unit is galvanically isolated from the handheld unit. The Silk'n ToothWave Device is electrically safe in accordance with medical device electrical safety standards (IEC 60601-1, IEC 60601-2-2 and IEC 60601-1-11).

The Silk'n ToothWave Device utilizes vibration and low power RF energy technologies. The action of the brush head has a vibration frequency up to 400Hz. The RF generator generates conductive RF energy at 3 MHz, with a maximal output power of 3W.

The handle or hand piece brush head is designed as a medium oval brush head and features an arrangement of bristles surrounding two low profile hidden RF electrodes and a silicon barrier located in-between the two electrodes. The handle or hand piece is equipped with an ON/OFF switch and indicator panel that indicates the device status (RF activation, vibration level, charging, or error).

The Silk'n Tootwave supports the placement of the following components:

- Charging cradle with USB cable & transparent base,
- Handle or hand piece,
- Brush head,
- USB wall adaptor,
- Warranty booklet
- User Manual

Following are the Silk'n Toothwave device specifications:

Model No.	H7001
Technology	DentalRF™ and vibration
Vibration	0, 275Hz, 300Hz or 400Hz
Radiofrequency	3MHz ±0.3MHz, up to 3W
Package size	(W) 165 (H) 227 (D) 80 [mm]
System weight	115 g
Adapter	YH-S06U0500600 (USA)
Input	100-240V, 50/60Hz, 0.2A
Output	5.0Vdc, 0.6A

Intended Use/Indication for Use:

The Silk'n Toothwave is a powered radiofrequency toothbrush intended to promote good oral hygiene, including reduction of plaque, and the prevention and treatment of gingivitis.

The Silk'n Toothwave is intended for over-the-counter use.

Performance Standards:

The Silk'n Toothwave device has been tested and complies with the following FDA recognized consensus standards:

[Rec. Number 19-4] ANSI AAMI ES 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
[Rec. Number 19-18] IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
[Rec. Number 19-14] IEC 60601-1-11 Edition 2.0 2015-01 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
[Rec. Number 6-389] IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential per
[Rec. Number 5-89] IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
[Rec. Number 13-79] IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
[Rec. Number 19-13] IEC 62133 Edition 2.0 2012-12 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
[Rec. Number 19-33] IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

[Rec. Number 4-238] ISO 20127 First edition 2005-03-15 Dentistry - Powered toothbrushes - General requirements and test methods

The device was also tested to comply with the following standards:

IEC 60335-2-52:2002, Safety of Household and Similar Electrical Appliances Part 2: Particular Requirements for Oral Hygiene Appliances.
EN55014-1:2006 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
EN55014-2:2006 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity
EN61000-3-2:2014 Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current up to and including 16A per phase)
EN61000-3-3:2013 Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection
EN61000-6-1:2007 Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – immunity for residential, commercial and light-industrial environments
EN55011: 2009+A1 Industrial, scientific and medical (ISM) radio-frequency disturbance characteristics – Limit and methods of measurement.

Non-Clinical (Bench) Performance Data:

Bench testing was conducted and submitted to the FDA in DEN190039. The purpose of the bench tests was to demonstrate that the Silk'n Toothwave device performs as expected under anticipated conditions of use and to verify that the device performance meets the device design requirements.

The following tests were conducted:

- Validation of the RF performance specifications including output power, voltage output, radiofrequency, pulse cycle, waveform, and pulse duration;
- Temperature performance testing to evaluate the temperature change of the device, structures of the oral cavity (including skin, tissue, and dental restorations), and toothpaste under worst-case conditions;
- An assessment of mechanical output specifications and physical properties including vibration frequency, tuft retention, brush head strength, and battery voltage; and
- Use life and durability testing.
- Software validation testing
- Biocompatibility testing

Pre-Clinical (Animal) Performance Data:

Animal studies were submitted to the FDA as part of DEN190039. No further animal studies were conducted and submitted in this 510(K)-file submission.

Clinical Performance Data:

A single-blinded, double arm randomized prospective study entitled "Safety and Efficacy of the ToothWaveTM Toothbrush (Model H7001) Home Use Device for Reduction of Dental Plaque and Calculus and Treatment and Prevention of Gingivitis ToothWave™ Clinical Study" was conducted and included a usability study. An additional self-selection study was also conducted in "Toothwave Usability and Self-Selection Study", and a clinical report with safety data was provided based on an additional single-blinded, double arm, randomized prospective study to evaluate the device used at the highest frequency.

These studies were submitted in DEN190039.

An additional single-blind, double arm prospective study was conducted to further evaluate the effect of ToothWave™ on calculus. The study was held at the Salus Research Centre, IN, USA, by Kim (RDH, PHD) and Jeff Milleman (DDS, MPA), in subjects with a moderate amount of visible calculus on the tongue side of their lower anterior teeth. Ninety (90) subjects were randomly assigned to either ToothWave™ or the control brush, a powered toothbrush. Treatment was defined as a timed two minutes teeth brushing, twice a day, during a three-month test period, returning at weeks 3, 6 and 12 for safety and Volpe-Manhold Index (V-MI) examinations. Each at home toothbrush session was self- documented in a designated diary.

At the completion of the study, the study result differences between baseline and V-MI examination at 6 and at 12 weeks were statistically significant with the control group (n=45) 7.7% at 6 weeks and 11.26% at 12 weeks vs the test group (n=42) which were 2.6% at 6 weeks and -1.47% at 12 weeks. After the study, participants were advised to return to their regular dentist appointments.

Substantial Equivalence:

The currently submitted Toothwave device is the exact same device as the FDA cleared Toothwave, which was previously submitted, and FDA cleared as part of the DeNovo application (DEN190039). Therefore, the current device includes the same design, technological features, user interface and hardware components as the cleared device. The safety features, compliance with safety standards, and all patient contact materials, remain unchanged and since no difference was made in the technological characteristics there are no safety concerns to be considered.

Additional clinical study as specified in the clinical performance data section to evaluate the performance of the ToothWave device on supragingival calculus levels. The clinical study results were added to the device user manual.

Based on the fact that all device characteristics remained unchanged, it can be concluded that the ToothWave device submitted in this 510k application is substantially equivalent to its predicate, the FDA cleared Toothwave device.