



September 17, 2020

Home Skinovations Ltd.
% Amit Goren
Regulatory Manager
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ISRAEL

Re: DEN190039
Trade/Device Name: ToothWave™
Regulation Number: 21 CFR 872.6866
Regulation Name: Radiofrequency Toothbrush
Regulatory Class: Class II
Product Code: QMJ
Dated: August 19, 2019
Received: August 22, 2019

Dear Amit Goren:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ToothWave™, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

ToothWave™ is a powered radiofrequency toothbrush intended to promote good oral hygiene, including reduction of plaque and the prevention and treatment of gingivitis. ToothWave™ is intended for over-the-counter use.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ToothWave™, and substantially equivalent devices of this generic type, into Class II under the generic name radiofrequency toothbrush.

FDA identifies this generic type of device as:

Radiofrequency toothbrush. A radiofrequency toothbrush is a device that consists of a handle containing a radiofrequency generator to deliver radiofrequency energy to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 22, 2019, FDA received your De Novo requesting classification of the ToothWave™. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ToothWave™ into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the ToothWave™ can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Thermal injury (mucosal or unintentional skin overheating/burn)	Non-clinical performance testing Software validation, verification, and hazard analysis Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Mechanical injury to the oral cavity	Electrical safety testing Non-clinical performance testing Labeling
Electromagnetic interference or electrical shock	Electrical safety testing Electromagnetic compatibility (EMC) testing Battery safety testing Labeling
Incorrect use or operation of the device causing harm or injury to the user	Non-clinical performance testing Usability evaluation Use life testing Electrical safety testing Labeling
Gingival irritation or recession, tooth sensitivity or pain by failure to identify correct population and condition	Label comprehension and self-selection study Labeling

In combination with the general controls of the FD&C Act, the radiofrequency toothbrush is subject to the following special controls:

- (1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested, and detailed protocols must be provided for each test conducted:
 - i. Validation of the RF performance specifications including output power, voltage output, radiofrequency, pulse cycle, waveform, and pulse duration;
 - ii. 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;
 - iii. An assessment of mechanical output specifications and physical properties including vibration frequency, tuft retention, brush head strength, and battery voltage; and
 - iv. Use life and durability testing.
- (2) A label comprehension and self-selection study must demonstrate that the intended user population can understand the package labeling and correctly choose the device for the indicated use.
- (3) Usability performance evaluation must demonstrate that the user can safely and correctly use the device, based solely on reading the directions for use.
- (4) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (5) Electrical safety, thermal safety, mechanical safety, battery safety, and electromagnetic compatibility (EMC) testing must be performed.
- (6) Software verification, validation, and hazard analysis must be performed.
- (7) Labeling must include:
 - i. Information on how the device operates, including images or illustrations;
 - ii. A detailed summary of the device technical specifications;
 - iii. A warning which states that the use of this device is not a substitute for regular visits to a dentist for routine clinical care;
 - iv. Instructions on how to clean and maintain the device; and
 - v. The use life and disposal of the components of the device.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the radiofrequency toothbrush they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Lauren Giles at 301-796-9552.

Sincerely,

for Malvina Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health