

**DE NOVO CLASSIFICATION REQUEST FOR  
TOOTHWAVE™**

**REGULATORY INFORMATION**

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.

**NEW REGULATION NUMBER:** 21 CFR 872.6866

**CLASSIFICATION:** Class II

**PRODUCT CODE:** QMJ

**BACKGROUND**

**DEVICE NAME:** ToothWave™

**SUBMISSION NUMBER:** DEN190039

**DATE DE NOVO RECEIVED:** August 22, 2019

**SPONSOR INFORMATION:**

Home Skinovations Ltd.  
Tabor Building, Shaar Yokneam  
Yoqneam Illit, 2069200  
ISRAEL

**INDICATIONS FOR USE**

ToothWave™ is indicated as follows:

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.

**LIMITATIONS**

Limitations on device use are achieved through the following statements included in the Instructions for Use Manual:

Contraindications:

“This device including all its parts must not be used by the following people: persons below the age of 18, those with limited physical, sensory or psychological capacities, those lacking experience or knowledge in how to use the device in a safe way, or those who do not understand the hazards involved.”

“Do not use the device if you:

- Have a pacemaker, internal defibrillator, another active implanted device, or if you have any medical concerns about using this device.
- Have a history of oral cancer or oropharyngeal cancer, or have any other type of cancer, or have pre-malignant lesions.
- Have an impaired immune system due to immunosuppressive diseases such as HIV, or you use immunosuppressive medication.
- Are pregnant or nursing.”

Warnings:

“The device is for home-use. The handle may be used by multiple persons, but for reasons of hygiene, each user must use their own brush head.”

“Use of this device is not a substitute for regular visits to the dentist for routine clinical care.”

“Consult your physician before use if you:

- Have concurrent conditions, such as heart disorders, seizures, uncontrolled high blood pressure, liver or kidney diseases.
- Have poorly controlled hormone disorders, such as diabetes or thyroid abnormalities.”

“Consult your dentist before use if you:

- Have had oral or gum surgery in the last two months.
- Have severely injured gums.”

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

**DEVICE DESCRIPTION**

**Overview**

The ToothWave™ is a handheld rechargeable electric toothbrush intended to promote oral hygiene, including reduction in plaque and prevention and treatment of gingivitis. The device is for over-the-counter (OTC) use. The device is comprised of the handle, the brush head, and recharging unit. The device utilizes radiofrequency (RF) energy and tactile vibration. The device is operated by a single-mode push button located on the handle/user interface board and includes

a set of light indicators informing the user of the device operation (RF activation, vibration level, charging, or error):

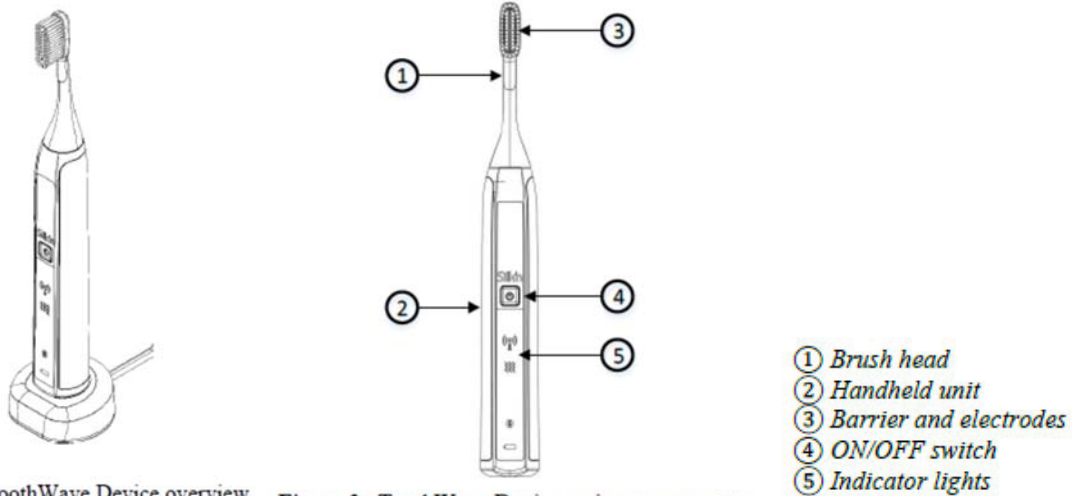


Figure 1: ToothWave Device overview. Figure 2 - ToothWave Device major components:

The device is charged using a rechargeable base unit that is inductively charged and galvanically isolated from the handle of the unit. The ToothWave™ toothbrush is equipped with four operation modes: no vibration (0 Hz), low vibration (275Hz), medium vibration (300Hz), and high vibration (400Hz). The RF generator generates low power conductive RF frequencies of 3.0 MHz±0.3MHz once turned on for operation; the maximum power output is 3W in all operating modes.

The handle is equipped with an ON/OFF switch and indicator panel that indicates the device status (RF activation, vibration level, charging, or error). The device is turned on by a long press of the ON/OFF switch and the mode is selected by cycling through the options using a short press of the ON/OFF switch.

### Brush Head

The device includes one small brush head with a contains tufts of bristles. Within the brush head, there are two RF electrodes. The silicon barrier is intended to protect the electrodes. The brush head is used to brush all surfaces of the teeth for 2 minutes with a slight vibration every 30 seconds. The user is intended to gently press the bristles against the teeth, and move the brush in circular movements, slowly and systematically from tooth to tooth. After 2 minutes, the device will shut down automatically. Each user must use their own brush head and is to be replaced every three months. In addition, the brush head is to be replaced if the bristles, silicone strip, or electrodes become loose, bent, damaged, or crushed.

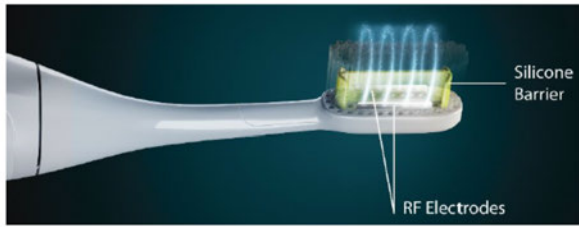


Figure 4: Graphic Representation of the ToothWave™ Brush Head



## Handheld Unit

The handheld unit has a plastic outside and contains the RF generator, vibration motor, RF electrode connector, microcontroller unit, and the control panel. The functions of each of the components of the handheld unit is as follows:

- RF generator - generates 3 MHz RF with maximal output power of 3W.
- Vibration motor – used for vibrating the brush head with a vibration frequency of: 0Hz, 275Hz, 300Hz and 400Hz.
- RF electrode connector - used for RF signal transference.
- Microcontroller unit - The microcontroller unit is responsible for the following tasks:
  - Monitoring the ON/OFF switch and controlling the LED indicators.
  - Controlling the RF.
  - Controlling the vibration of the brush head.
- Control panel - The control panel includes the ON/OFF switch and 6 indicator LEDs. There are six LED indicators located on the front of the handheld brush, four white indicators indicating the selected operation mode, the fifth orange LED indicates the battery status mode, and the sixth green LED indicates the charging mode.

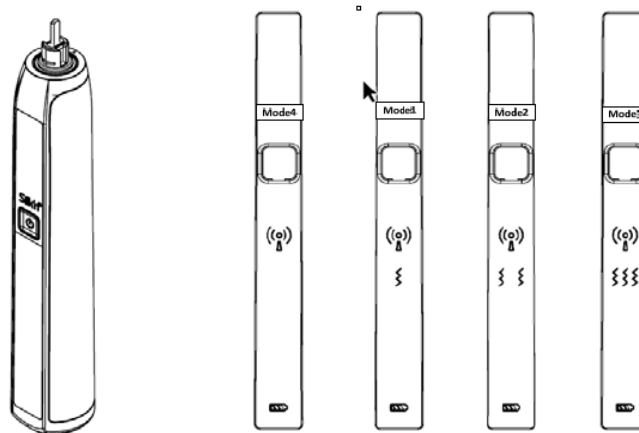


Figure 1 - Handheld Unit and Control Panel

## Adapter and Charger Base

There is one US adapter for the device. This adapter connects the charging base to the wall outlet. The charger base unit runs on 5V DC. An AC/DC power adapter with USB output of 5V DC is connected to the charger base, which transmits 60 kHz electromagnetic energy to charge the internal battery in the handheld unit. Following are the power adapter input specifications:

- Input voltage: 100-240V
- Input Frequency: 50/60Hz
- Input Current: 0.2A

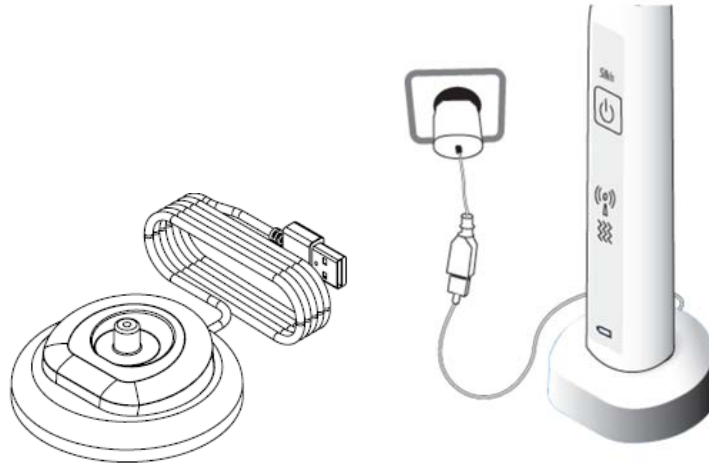


Figure 2 - Charger Base Unit and Adapter

## Device Specifications

Model no.	H7001	Time from maximum storage temperature between uses to maximum operating temperature with ambient temperature of 20°C	30 minutes
Technology	DentalRF™ and vibration	Protection against electric shock	Class I medical equipment type BF applied part
Vibration	0; 275Hz; 300Hz or 400Hz (± 5%)	Adapter	YH-S06U0500600 (USA)
Radio frequency	3MHz ±0.3MHz; up to 3W	Input:	100 – 240V; 50/60Hz; 0.2A
Package size	(W)165 (H)227 (D)80 [mm]	Output:	5.0Vdc; 0.6A
System weight	115g	Mode of operation	Non-continuous
Transport & storage between uses and storage condition	Temperature: - 40 to 70°C Relative humidity : 10 to 90%rH Atmospheric pressure: 500 to 1060hPa	Waterproof rating: USB adapter (IPX4)	Protection assured against water splashing
Operating conditions	Temperature: 5 to 40°C Relative humidity: 15 to 90%rH Atmospheric pressure: 700 to 1060hPa	Charging cradle (IPX7) Handle (IP67)	Protection assured against water immersion at a depth of up to 1 meter, for a maximum of 30 minutes.
Time from minimum storage temperature between uses to minimum operating temperature with ambient temperature of 20°C	30 minutes	The device was tested and complies with	IEC 60601-1 (Safety) IEC 60601-2-2 (RF Safety) IEC 60601-1-2 (EMC) IEC 60601-1-11 (Environment)
		Service life of the equipment	5 years

## **SUMMARY OF NONCLINICAL/BENCH STUDIES**

Non-clinical/bench studies conducted on the ToothWave™ device contribute to a demonstration of the device performance characteristics:

### **BIOCOMPATIBILITY/MATERIALS**

The patient contacting component of the ToothWave™. The device was evaluated with respect to its intended use per ISO 10993-1:2003, Biological evaluation of medical devices and FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’”. Testing was performed on final finished device. The device is a surface device in contact with intact skin and mucosal membrane for a limited duration. The following tests were performed on the toothbrush body/brush head, silicon barrier, RF brush head electrodes, and toothbrush bristles.

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10

The results supported the biocompatibility of the ToothWave™.

### **SHELF LIFE/STERILITY**

The device is not provided sterile nor end user sterilized. The handle may be used by multiple persons, but for reasons of hygiene, each user must use their own brush head. After use, the brush head and handle are to be washed under running water to remove any toothpaste or debris. If there remains any stuck on debris, the brush head is to be replaced.

The ToothWave™ brush head and handle/handpiece underwent a life time test to assess device durability. The lifetime test results demonstrated the durability, stability and reliable performance of both the brush head and handpiece/handle for the designated lifetime of the ToothWave toothbrush (3 months for the brush head and 5 years for the handle/hand piece).

### **ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY**

#### **Electromagnetic Compatibility (EMC):**

The ToothWave™ was evaluated for conformance to IEC 60601-1-2 Edition 4.0 (2014) and was found to comply with all applicable requirements of this EMC testing standard.

#### **Electrical Safety:**

The ToothWave™ was evaluated for conformance to AAMI/ANSI 60601-1, (2012) medical electrical equipment - part 1: general requirements for basic safety and essential

performance (IEC 60601-1:2005, Mod). Review of the results concluded that the device complies with all the electrical safety requirements specified in this standard.

The following additional electrical safety and EMC testing was performed:

- 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.
- IEC 60601-2-2: 2017, Medical electric equipment, part 2: particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency accessories.
- IEC 60601-1-6:2010, medical electrical equipment part 1-6, general requirements for safety – collateral standard: usability.
- IEC 62304:2015, Medical device software, software life-cycle processes.
- ISO 20127:2005, Dentistry -- Powered toothbrushes -- General requirements and test methods.
- IEC 60335-2-52:2002, Safety of Household and Similar Electrical Appliances Part 2: Particular Requirements for Oral Hygiene Appliances. IEC 62133:2012, Secondary Cells and Batteries Containing Alkaline or Other Non- Acid Electrolytes – Safety Requirements for Portable Sealed Secondary
- 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.

#### **MAGNETIC RESONANCE (MR) COMPATIBILITY**

The device has not been tested for MRI compatibility and should not be used in the vicinity of an MRI device.

## SOFTWARE

The ToothWave™ toothbrush consists of internal electrical components, a firmware component, and a man machine interface. The man machine interface includes a control panel including button and Indicators. The software is responsible for initialize and power up, standby, charger, motor vibration, RF PWM, and error state.

The ToothWave™ toothbrush device software Level of Concern is Moderate following the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). Consequently, the software verification and validation testing provided in this submission complies with the requirements for a Moderate level of concern. The software verification & validation performed on the ToothWave™ toothbrush software demonstrated that the software can control the user interface with device (On/Off switch and mode selection), check the hardware status and inform the user through the indicator lights of device status, etc.

## PERFORMANCE TESTING - BENCH

Non-clinical performance tests were conducted to demonstrate mechanical integrity and functionality of the ToothWave™. There are three sections of testing conducted: temperature tests, mechanical & lifetime performance testing, and ISO 20127 testing. The table below (Table 1) summarizes each of these bench tests:

<b>Temperature Tests: The temperature tests were conducted to evaluate the thermal safety of the ToothWave™ toothbrush device to demonstrate that intentional and unintentional contact with the oral cavity, other body tissues, contact with metal-containing dental structures and different types of toothpaste does not result in overheating, risk of burns or significant temperature elevation associated with its use.</b>			
<b>Test</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Results</b>
Skin and Tissue Temperature Safety Test	The experiment was intended to simulate intentional and unintentional contact of the ToothWave device brush head with the oral cavity (gums, tongue) and user skin (arm, neck, cheek) and tissue areas during use. A statistical analysis comparing the oral cavity, skin and tissue temperatures before and after application of the ToothWave device was evaluated.	RF current does not cause an increase in the local temperature of the evaluated body parts, even when statically and continuously attached to it for 2 minutes and within physiological range (35 – 37°C)	PASS
Device Safety on Dental Structures Test	The study objective was to determine the effect of different metal-containing dental structures (ceramic and CoCr crowns, gold crowns, amalgam fillings, and metal braces) on the brush temperature during brushing with the ToothWave device, within a simulated physiological environment. The treatment included different settings: with and without vibration, as well as static and dynamic operation.	The temperatures of the toothbrush measured during these experiments is stable and reproducible and that the temperature achieved during brushing will be below 42°C based on IEC 60601-2-2.	PASS



Analysis of the toothpaste temperatures during RF activation	A series of experiments were conducted in order to study the temperature increase of different marketed toothpastes following 2 minutes of RF activation using the ToothWave device with and without vibration. The temperature of several spot within the brush head was measured and documented before and after each treatment.	The measured temperature during RF activation will be below 30°C.	PASS
<b>Mechanical and Lifetime Performance Tests: Testing was conducted to evaluate the mechanical and lifetime performance of the device including corrosion resistance, durability, tensile force, bending, flexural strength and the tuft retention force. The ToothWave™ brush head and handle were evaluated for durability during its life time under worst-case simulated use test conditions.</b>			
<b>Test</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Results</b>
RF Generator Test	The working frequency range of the RF frequency were tested for each mode to verify the characteristics as specified in the Device Specifications including input voltage, output frequency, output voltage, and output power under load and no-load conditions.	The RF Generator meet the design specifications of the device	PASS
Motor Driver Test	The motor driver circuit was tested to evaluates the ability to apply the different modes of the driver input signals to produce the vibration at the different frequencies (275Hz, 300Hz, 400Hz), input current, voltage capability.	The differential driver output measurements for each vibration mode is within the specification limits	PASS
Brush Head Worst Case Lifetime Test	Testing was conducted to determine the wear on the brush head after three months of worst-case simulated brushing on extracted teeth containing orthodontic brackets. Worst-case condition for brushing force, abrasive toothpaste, teeth specimen, frequency, and movement direction were evaluated under simulated conditions. Evaluation of the functionality and wear/damage to the bristles, silicone barrier, RF electrodes, and orthodontic braces were observed.	Based on literature a Conforti index score of 1 -Light Wear for the bristles was selected based on use life of 3 months. In addition, the bristles, RF electrodes and silicone barrier is to remain in place.	PASS
The Durability of the Electric RF Toothbrush Test	Testing was conducted to evaluate the durability of the brush head by mating/un-mating of the RF contacts, barrier retention force, barrier bending, brush head flexural strength, tuft retention and handle during the simulated use life of the device (brush head – 3 months, handle – 5 years).	The device functions as intended and there is no excessive wear or damage observed by visual inspection.	PASS
System Verification and Validation Test	Evaluation of the device design and performance of each system including dimensional characteristics, operating environment specification, power adapter specification, system characteristics, handpiece, system capability, operational, and safety.	Results are according to the requirements in the System Requirements	PASS
<b>ISO 20127 Test: ISO 20127:2005 specifies requirements and test methods for the physical properties of powered toothbrushes in order to promote the safety of these products for their intended use.</b>			
<b>Test</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Results</b>
ISO 20127 - Dentistry – Power toothbrushes – General	Evaluate the compliance of the device to ISO 20127:2005	Test method and requirements established in ISO 20127:2005	PASS

requirements and test methods			
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**SUMMARY OF CLINICAL INFORMATION**

A single-blinded, double arm randomized prospective study entitled “Safety and Efficacy of the ToothWave™ 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.

**TOOTHWAVE DEVICE EFFICACY AND SAFETY CLINICAL STUDY**

*Study Report Title*

“Safety and Efficacy of the ToothWave™ Toothbrush (Model H7001) Home Use Device for Reduction of Dental Plaque and Calculus and Treatment and Prevention of Gingivitis ToothWave™ Clinical Study”

The clinical study included a usability study and self-selection study in “Toothwave Usability and Self-Selection Study”

*Objective*

To evaluate the effect of an RF-utilizing toothbrush on plaque, calculus and gingivitis compared to a control standard American Dental Association (ADA)-accepted and FDA-registered powered toothbrush.

*Study Endpoints*

- Efficacy assessment:
  - Efficacy was evaluated by examiners trained in the assessment of gingivitis, dental plaque and calculus.
  
- Primary endpoint:
  - A significant reduction from baseline in the average scores of plaque and gingivitis compared to an ADA accepted power toothbrush, after 6 weeks of treatment.
  
- Secondary endpoints:
  - A significant reduction from baseline in calculus in the treatment group as evaluated by a validated calculus index, following 6 weeks treatment.
  - Subjective impression by a test subject questionnaire on oral hygiene status in the treatment group, following 6 weeks of treatment.
  
- Safety Assessment

Assessment of device safety was conducted using the following measures:

- Dental examination.
- Reported errors and near errors using the device.
- Documentation of device malfunctions, which relate to device safety.
- Documentation of device-related adverse events
- Documentation of non-device related adverse events (secondary endpoint)

*Method*

This was a single-blinded, double arm, randomized prospective study, including (b) (4) clinic visits conducted every (b) (4) weeks. During each visit, a safety assessment was conducted via dental examination, and compliance with study protocol was evaluated. At baseline and 6 weeks of brushing (visits (b) (4) and (b) (4) respectively), all subjects were assessed for amount of plaque using the Rustogi Modified Navy Plaque Index (RMNPI); amount of calculus on the lingual surface of the anterior mandibular teeth using the Volpe-Manhold Index (V-MI); and gingivitis using the Modified Gingival Index (MGI) and Gingival Bleeding Index (GBI) measures. Subjects were randomized to one of two study groups: subjects in the treatment group received the ToothWave™ with radiofrequency and used at the low vibration speed setting, and subjects in the control group received a power toothbrush without radiofrequency. The subjects in the treatment group participated in a usability study prior to beginning the prospective study for safety and effectiveness. All subjects were instructed to perform twice daily brushing at home based on directions for use during the 6 week test period. Reduction from baseline results (mean scores) were compared within each group and between the group 6 weeks follow-up, and statistical analyses were conducted using the Mann Whitney non-parametric model and the repeated measures model.

*Population and Sample Size*

The study population included generally healthy adult subjects between the ages of 18 – 70 who were selected for participation based on having a moderate level of gingivitis, calculus, and a level of plaque consistent with levels of plaque in “plaque formers”, those who are consistently observed to have visible plaque covering their teeth. The treatment group included 45 subjects and the control group 41 subjects.

Table - Patient Accountability

	N	%
Number of Screened Subjects	(b) (4)	
Number of Screen Failures		
Number of Subjects Withdrew Consent Prior to Randomization		
Number of Randomized Subjects ( <b>ITT Analysis Set</b> )	86	91.5
Number of Subjects Withdrew Consent after Randomization	(b) (4)	

Table - Baseline Demographic Characteristics (ITT)

	<i>Characteristic</i>	<i>ToothWave™ N=45</i>	<i>Control N=41</i>	<i>Overall</i>
<b>Age</b>	Mean age (SD)	44.9 (14.42)	46 (11.52)	45.4(13.05)
	Age range	18-70	23-66	18-70
<b>Gender</b>	Male (%)	15 (33.3%)	13 (31.7%)	28 (32.6%)
	Female (%)	30 (66.7%)	28 (68.3%)	58 (67.4%)
<b>Race</b>	Caucasian (%)	36 (80%)	35 (85.4%)	71 (82.6%)
	Black, Non-Hispanic (%)	6 (13.3%)	4 (9.8%)	10 (11.6%)
	Asian Pacific Islander (%)	2 (4.4%)	1 (2.4%)	2 (2.3%)
	American Indian / Alaskan Native (%)	1 (2.2%)	1 (2.4%)	2 (2.3%)

*Results*

A total of 86 subjects (45 in the treatment group and 41 in the control) completed the study and comprise the cohort for safety and efficacy analyses. At baseline, the test groups did not differ significantly in the efficacy measurement mean scores. Following 6 weeks of brushing the test group showed statistically significant reductions in all the tested measures compared to the control group. In addition, the delta values of all measured scores were statistically significantly greater in the treatment group compared to the control. No device related adverse events were reported during the study.

Table - Calculated difference (delta) from baseline following 6 weeks of twice daily brushings

		N (randomized)	N (completed)	Baseline Mean (SD)	6 weeks Mean (SD)	Delta Mean (SD)	mean percent change
				[Redacted]			
<b>MGI</b>	Treat	45	44	(b) (4)		-44.99	
	Control	41	41	[Redacted]		-31.35	
<b>GBI</b>	Treat	45	44	[Redacted]		-34.57	
	Control	41	41	[Redacted]		-2.78	
<b>RMNPI</b>	Treat	45	44	[Redacted]		-25.19	
	Control	41	41	[Redacted]		-14.93	

\*In a post hoc analysis, the results showed a 2% accumulation of tartar in the treatment group and 14% accumulation of tartar in the control group.

## TOOTHWAVE USABILITY & SELF-SELECTION CLINICAL STUDY

### *Objective*

To test that the ToothWave™ (Model H7001) device may be used properly and safely by potential lay end users, under actual use conditions. Additionally, this evaluation is intended to confirm that contraindicated lay users successfully self-exclude themselves from use of the device and that the labeling content is accurately understood by potential lay end users.

### *Investigation Design*

Two studies were conducted and summarized in study report DO116538A. The usability study component was conducted as part of the “Safety and Efficacy of the ToothWave™ Toothbrush (Model H7001) Home Use Device for Reduction of Dental Plaque and Calculus and Treatment and Prevention of Gingivitis ToothWave™ Clinical Study” (Study protocol #DO116217A) with the 45 study subjects assigned to the treatment group. The second study (Study Protocol #DO116508A) was conducted in 10 subjects and was aimed to assure self-exclusion of potential lay users who are not eligible for device use. All of the participants that were included in this user performance evaluation (n=55) received the toothbrushes in their original package with the complete user manual, as intended for marketing. The 45 subjects in the usability evaluation were asked to correctly identify themselves as potential eligible lay end users of the ToothWave™ toothbrush and perform a single treatment session according to the device instructions while being observed only (without intervention.) The self-selection evaluation included 10 subjects (5 potential end users and 5 contraindicated subjects), who independently decided whether they were eligible or contraindicated for device use, based on the device labeling (user manual and box label), but did not perform any treatment. The usability subjects (n=45) completed a post-treatment questionnaire and the self-selection subjects (n=10) completed post-reading questionnaire. All subjects completed a labeling comprehension exam.

		<b>Usability evaluation</b>	<b>Self-selection study</b>	<b>Total</b>
<b>Age</b>	<b>N</b>	45	10	55
	<b>Mean</b>	44.9	49.1	45.7
	<b>SD</b>	14.4	22.3	16.0
	<b>Min</b>	18	22	18
	<b>Max</b>	70	84	84
	<b>Med</b>	46	41	45

<b>Table 3: Distribution of gender</b>						
<b>Gender</b>	<b>Usability evaluation</b>		<b>Self-selection study</b>		<b>Total</b>	
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Female</b>	30	66.7%	8	80%	38	69%
<b>Male</b>	15	33.3%	2	20%	17	31%

*Success Criteria*

Study success was determined as study subjects assigned to the use of ToothWave™ would properly and safely use the device under actual use conditions/ability to correctly understand the user manual and device labeling materials.

All 55 participants in the usability and self-selection study would demonstrate labeling comprehension in the labeling comprehension exam.

For the self-selection study, 5 intended users would identify themselves as potential users of the device, while the 5 contraindicated subjects would be able to self-exclude from use of the device.

*Results*

Usability evaluation:

Subjects' age ranged from 18 to 70 years old, with an average age of 44.9 (±14.4) years. 30 (66.7%) subjects were females and 15 (33.3%) subjects were males. All of the eligible 45 subjects identified themselves as potential users of the device and completed the device related tasks in less than 10 minutes with no requests for assistance. No adverse events were reported during the treatment. Results of post treatment questionnaires and labeling comprehension test indicated a good experience of the potential lay users, who found it easy to understand the instructions for use and perform the device related tasks.

Self-selection study:

Subjects' age ranged from 22 to 84 years old, with an average age of 49.1 (±22.3) years. Eight (80%) subjects were females and 2 (20%) subjects were males. All 5 eligible potential lay end users identified themselves as eligible to use the device and all 5 contraindicated subjects self-excluded themselves from use, based on the device labeling materials (user manual and box label).

**THE TOOTHWAVE SAFETY (HIGH VIBRATION SPEED) CLINICAL STUDY REPORT**

An additional clinical safety analysis was conducted based on a second comparative clinical study conducted with the ToothWave™ device used with the high vibration frequency (400Hz) in conjunction with the RF activation to evaluate (n = 86) in a single-blind, randomized double arm prospective study with subjects randomized to a group using ToothWave™ (n=43) or a control power toothbrush, for 6 weeks with an oral soft tissue examination conducted every 2 weeks with no adverse events reported.

### Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

### LABELING

The sponsor provided labeling includes a user manual and packaging label for the ToothWave™. The user manual includes the Indications for Use and a description of how the device works, how to use the device, maintenance of the device, and warnings/precautions/contraindications for use of the device. The user manual also summarizes the clinical data. The device is intended for over-the-counter use, therefore, the language used in the user manual uses common, layperson language. To clarify the use of the device with respect to the supporting data provided to demonstrate safety and effectiveness, the device labeling was revised to including the following:

- Contraindication that this device including all its parts must not be used by the following people: children, adults below the age of 18, those with limited physical, sensory or psychological capacities, those lacking experience or knowledge in how to use the device in a safe way, or those who do not understand the hazards involved.
- The device is for home-use. The handle may be used by multiple person, but for reasons of hygiene, each user must use their own brush head.
- The Use of the device is not a substitute for regular visits to the dentist for routine clinical care.
- To consult your physician/dentist before use if you have conditions such as heart disorder, seizures, uncontrolled high blood pressure, liver or kidney disease, diabetes, oral or gum surgery in the last two months, or severely injured gums.

The user manual describes the packaging contents of the device, the controls, and settings. The device is used for two (2) minutes, morning and evening to brush the teeth and gums. The brush head is to be replaced every three (3) months. The user manual states to check the brush head prior to each use for signs of damage such as excessive wear and/or biofilm accumulation. The brush head is to be replaced if there are signs of damage. The user manual contains instructions of the cleaning and maintenance of the device. Directions for disposal of the components are the device are provided within the user manual. In addition, the user manual identifies the technical specifications of the device including the radio frequency (3MHz ±0.3MHz; up to 3W) and vibration (0; 275Hz; 300Hz or 400Hz (± 5%)). The company name and contact information is provided in the user manual.

## **RISKS TO HEALTH**

The table below identifies the risks to health that may be associated with use of the radiofrequency toothbrush and the measures necessary to mitigate these risks.

Table – Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
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

## **SPECIAL CONTROLS**

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.

#### **BENEFIT-RISK DETERMINATION**

The benefits of the device align with the benefits of other powered vibrating bristle head toothbrushes, to reduce/remove plaque on tooth surfaces and treatment and prevention of gingivitis, an inflammatory condition of gingiva secondary to plaque accumulation; the daily use of the ToothWave™ device as directed can provide the benefit of reduced plaque and reduced plaque accumulation, and treatment and prevention of gingivitis. The probable benefits of the ToothWave™ device are based on the clinical performance testing provided, and the improvements seen in plaque reduction and gingival bleeding is substantial. The label comprehension and self-selection study was conducted to assess the effectiveness of the package labeling for the intended OTC users to understand and correctly choose this device for themselves to reduce plaque and for treatment and prevention of gingivitis. The ToothWave™ device labeling appears to mitigate potential user error associated with device use and to allow the user to identify the correct population and condition for the device. The label comprehension and self-selection study demonstrated that the intended OTC users can understand the package labeling and correctly choose this device for themselves for reduction of plaque and treatment and prevention of gingivitis.

The expected adverse events include gingival irritation, damage to gingival texture and contour, and tooth sensitivity. Based on the clinical performance testing provided, including the report of no adverse events, the probability of each of these adverse events is very low. Patients reported

acceptable rates of satisfaction. Additional factors to be considered in determining probable risks and benefits for the ToothWave™ device include: the limitations of the use of the device per the instructions in the labeling. One such limitation is that the device should not be used if the consumer experiences continued gingival irritation after two weeks of regular use. The safety and effectiveness of the ToothWave™ device has not been established for subjects with implanted electrical devices such as pacemakers. Both limitations are described in the package labeling.

In conclusion, given the available information summarized above, the data supports that for general population consumers, the probable benefits outweigh the probable risks for the ToothWave™ device to reduce plaque and for treatment and prevention of gingivitis.

#### Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

#### Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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.

The probable benefits outweigh the probable risks for the ToothWave™. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

#### CONCLUSION

The De Novo for the ToothWave™ is granted and the device is classified as follows:

Product Code: QMJ  
Device Type: Radiofrequency toothbrush  
Regulation Number: 21 CFR 872.6866  
Class: II