February 5, 2021

Sonendo, Inc
Lyle VerPlanck
Director of Regulatory Affairs & Quality Assurance
26061 Merit Circle, Suite 102
Laguna Hills, California 92653

Re: K203302
Trade/Device Name: GentleWave X
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: November 6, 2020
Received: November 9, 2020

Dear Lyle VerPlanck:

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, M.ChE.
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203302

Device Name
GentleWave X

Indications for Use *(Describe)*
The Sonendo GentleWave X System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave Molar Procedure Instrument or Molar CrossFire™ Procedure Instrument, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave Anterior/Premolar Procedure Instrument, the System is indicated for anterior and premolar teeth. When used with the Sonendo GentleWave Premolar CrossFire™ Procedure Instrument, the system is indicated for premolar teeth.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

General Information

510(k) number:	K203302
Date Summary Prepared:	February 3, 2021
Submitted by:	Sonendo, Inc. 22061 Merit Circle, Suite 102 Laguna Hills, CA 92653
Establishment Registration Number:	3010817521
Contact Person:	Lyle VerPlanck Director of Regulatory Affairs & Quality Assurance Phone: (949) 667-7260 FAX: (949) 305-5201 E-mail: lverplanck@sonendo.com
Reason for Premarket Notification:	New model of GentleWave System
Trade Name:	GentleWave X
Regulation Name:	Ultrasonic Scaler
Review Panel :	Dental
Classification Regulation:	872.4850
Product Code:	ELC
Regulatory Class:	Class II
Predicate Device:	Sonendo GentleWave System via K160905

Device Description

The Sonendo GentleWave X System is a medical device intended to prepare, clean and irrigate root canals. The Sonendo GentleWave X System is comprised of a Console, and disposable single-use Handpieces and accessories. The Handpiece is offered for molar, anterior and premolar treatments. A Molar Handpiece (original or CrossFire™ model) is intended to be used on 1st and 2nd molar teeth. An Anterior/Premolar (APM) Handpiece is intended to be used on anterior and pre-molar teeth and CrossFire™ Premolar Handpiece is intended for pre-molar teeth only.

The Sonendo GentleWave X System delivers a stream of treatment fluids into the pulp chamber of the tooth. The treatment fluids delivered to the tooth are 3% Sodium Hypochlorite (NaOCl) solution and an 8% Ethylenediaminetetraacetic acid (EDTA) utilized in traditional endodontic treatments.

The design of this device incorporated the consensus standards listed in Table 1.

Table 1 - Recognized Consensus Standards

Recognition Number	Standard Designation Number	Standard Title
2-258	ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2-245	ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-174	ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
2-255	ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
19-4	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-8	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perform
4-262	IEC 80601-2-60	Particular requirements for the basic safety and essential performance of dental equipment
5-114	IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices

Indications for Use

The Sonendo GentleWave X System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave Molar Procedure Instrument orMolar CrossFire™ Procedure Instrument, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave Anterior/Premolar Procedure Instrument, the System is indicated for anterior and premolar teeth. When used with the Sonendo GentleWave Premolar CrossFire™ Procedure Instrument, the system is indicated for premolar teeth.

Substantial Equivalence Summary and Discussion

The table below includes a comparison between the new device and the predicate device:

Table 1 - Comparison of Predicate and Proposed Devices

Characteristic	Predicate Device	Proposed Device
510(k) Clearance #	K160905	TBD
Console Model	GentleWave®	GentleWave™ X
Indications for Use	The Sonendo GentleWave System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave Molar Handpiece, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave Anterior/Premolar Handpiece, the System is indicated for anterior and premolar teeth.	The Sonendo GentleWave X System is intended to prepare, clean, and irrigate teeth indicated for root canal therapy. When used with the Sonendo GentleWave Molar Procedure Instrument or Molar CrossFire™ Procedure Instrument, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave Anterior/Premolar Procedure Instrument, the System is indicated for anterior and premolar teeth. When used with the Sonendo GentleWave Premolar CrossFire™ Procedure Instrument, the system is indicated for premolar teeth.
New Contraindications	---	Primary dentition Patients with sensitivity to NaOCl and / or EDTA
Function	Preparation, cleaning and irrigation of root canal	Identical as predicate

Characteristic	Predicate Device	Proposed Device
Principal of Operation	Generation of hydroacoustic waves and fluid motion via application of sonic energy	Identical as predicate
Treatment Site	Root Canal	Identical as predicate
Components	Control Unit Irrigation reservoirs Foot pedal Handpiece Hand piece Accessories	Identical as predicate
Duration of treatment application	7 minutes or less	Identical as predicate
Treatment fluid Concentration	Fixed	Identical as predicate
Fluid Containers	1 × 500 mL NaOCl irrigation solution 1 × 250 mL EDTA irrigation solution 1 × 2000 mL distilled water for irrigation	1 × 1360 mL NaOCl irrigation solution 1 × 540 mL EDTA irrigation solution 1 × 2650 mL distilled water for irrigation
Material	Medical grade material	Identical as predicate
Biocompatibility	Biocompatible per 10993	Identical as predicate
Handpiece models	Molar Handpiece (original model), Anterior/Premolar Handpiece	Molar Handpiece (original or CrossFire™ model), Anterior/Premolar Handpiece, Premolar CrossFire™ model Handpiece
Handpiece Sterilization	Sterile (Gamma) Single use Sterility Assurance Level (SAL) 10^{-6}	Identical as predicate
Consumable Shelf Life	1 year	Identical as predicate

The proposed device has the same intended use, function, principal of operation, control mechanism, sterilization and shelf life as the predicate device. The indications for use is slightly changed to add new models of the handpiece within the scope of the predicate device indications

for use. To highlight that the use of GentleWave X system is limited to treat permanent teeth only, contraindication for primary dentition teeth is added. Furthermore, to minimize any potential adverse reaction, the device is contraindicated for use on patients with a known sensitivity to NaOCl and/ or EDTA. The new handpiece models are added to increase manufacturability and there is no change in the handpiece operating principal. The new Console model has increased capacity, with larger bottle sizes to facilitate more treatments cycles. The new model is designed to improve customer interface, product reliability and manufacturability. Performance testing is completed to show the equivalency between the proposed and predicate devices.

Non-Clinical Performance Testing

All necessary performance testing has been conducted on the Sonendo GentleWave System X to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. The following bench testing in accordance with standards listed in Table 1 was performed and passed to support the substantial equivalence of the subject device:

- Performance Verification
    - Thermal test
    - Cavitation test
    - Hydroacoustic test
    - Cleaning test
    - Apical pressure test
    - Apical extrusion test
- Human Factor Evaluation per the FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices"
- Software Validation for moderate level of concern per the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- Biocompatibility
    - Cytotoxicity, sensitization, irritation, material mediated pyrogenicity, and acute systemic toxicity
- Electromagnetic Compliance and Electrical Safety

Clinical Data

No clinical data is submitted in support of this Premarket Notification.

Conclusion

The Sonendo GentleWave X System is a new model of the existing Sonendo GentleWave® System. The Sonendo GentleWave X System is substantially equivalent to the Sonendo GentleWave System cleared under premarket notification K160905.