Sonendo, Inc
Eric Simon
Director, Regulatory Affairs and Quality Assurance
26061 Merit Circle
Laguna Hills, California 92653

March 16, 2019

Re: K190359
Trade/Device Name: Sonendo GentleWave System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: February 14, 2019
Received: February 15, 2019

Dear Eric Simon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.03.16 10:08:18 -04'00'

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K190359

Device Name

Sonendo GentleWave(R) System

Indications for Use *(Describe)*

The Sonendo GentleWave(R) 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Sonendo, Inc.
DATE PREPARED:	February 14, 2019
CONTACT PERSON:	Eric Simon 26061 Merit Circle, Suite 102 Laguna Hills, CA 92653 Phone: 949.766.3636 Fax: 949.305.5201
TRADE NAME:	Sonendo GentleWave® System
COMMON NAME:	Sonic Cleaning and Irrigation System
CLASSIFICATION NAME:	Ultrasonic Scaler
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 872.4850
REVIEWING PANEL:	Dental
ESTABLISHMENT REGISTRATION NO.	3010817521
PRODUCT CODE	ELC
PREDICATE DEVICES:	Sonendo GentleWave® System (K160905)

Description of the Device Subject to Premarket Notification:
The Sonendo GentleWave® System is a medical device intended to prepare, clean and irrigate root canals. The Sonendo GentleWave® System is comprised of a Console, and a disposable single-use Handpiece. The Handpiece is offered in two versions: a Molar Handpiece which is intended to be used on 1st and 2nd molar teeth and an Anterior/Premolar Handpiece which is intended to be used on anterior and pre-molar teeth.

Indication 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.

Substantially Equivalent To:
The Sonendo GentleWave® System is a modified device of the existing Sonendo GentleWave® System. The modified Sonendo GentleWave® System is substantially equivalent in intended use, principal of operation and technological characteristics to the Sonendo GentleWave® System cleared under premarket notification K160905.

Technical Characteristics:
The Sonendo GentleWave® System has similar physical and technical characteristics to the predicate device. The modification to the Molar Handpiece design is merely to decrease the footprint in which the end user is currently required to store the device prior to use and to reduce the waste footprint of the device. The modification separates the handle and tip (sealing surface/nozzle) portions of the handpiece with the handle portion changing from a single-use to a reusable/re-sterilizable component whereas the tip portion of the handpiece remains a single-use gamma irradiated sterilized component.

Technical Characteristics	**Sonendo GentleWave® System (modified)**	**Sonendo GentleWave® System (K160905)**
Function	Preparation, cleaning and irrigation or root canal	SAME
Principle of Operation	Generation of hydroacoustic waves and fluid motion. The tip of the device is placed inside the tooth during cleaning. Hydroacoustics are created by the water stream flowing through the guide tube and coming into contact with the fluid inside the tooth at the distal tip. The fluid stream is dispersed and deflected by the distal end plate of the tube creating hydrodynamics (fluid motion) within the tooth.	SAME
Treatment Site	Root canal	SAME
Components	Control Unit Irrigation reservoirs Foot pedal Handpiece Accessories	SAME
Treatment times	Fixed or User selected	SAME
Treatment fluid concentration	Default mode at the concentration value identical to the predicate or 3 setting options to decrease the concentrations of the fluids	SAME
Handpiece Sterilization	Molar Handpiece Handle: Steam sterilized via autoclave Molar Handpiece Tip: Gamma Irradiation	Gamma Irradiation
Handpiece Sterility Assurance Level (SAL)	10^{-6}	SAME
Consumable Shelf Life	1 Year	SAME

Each of the technical attributes are present in the predicate device. The modification to Handpiece does not affect the substantial equivalent nature of the modified device, as this change is merely to increase manufacturability, decrease the footprint in which the end user is currently required to store the device prior to use, and to reduce the waste footprint of the device. The modification separates the handle and tip (sealing interface/ nozzle) portions of the handpiece with the handle portion changing from a single-use to a reusable/re-sterilizable component whereas the tip portion of the handpiece remains a single-use gamma irradiated sterilized component.

Performance Data:
All necessary performance testing has been conducted for the Sonendo GentleWave® System to assure substantial equivalence to the predicate device and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Testing included:

- Root Canal Cleaning Efficacy
- Apical Pressure
- Sterilization (Sterility Assurance)

Basis for Determination of Substantial Equivalence:
The indications for use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The Sonendo GentleWave® System is similar to the predicate device and is determined by Sonendo, Inc. to be substantially equivalent to the predicate device.