DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 3, 2016

Sonenedo, Inc.
Mr. Dan W. Miller
Sr. Vice President of Regulatory Affairs,
Clinical Affairs, and Quality Assurance
26061 Merit Circle, Suite 102
Laguna Hills, Ca 92653

Re: K160905
Trade/Device Name: Sonendi Gentle Wave® System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: May 2, 2016
Received: May 4, 2016

Dear Mr. Miller:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160905

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(R) Molar Handpiece, the System is indicated for 1st and 2nd molar teeth. When used with the Sonendo GentleWave(R) 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.

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6. 510(k) K160905 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:	March 31, 2016
CONTACT PERSON:	Dan W. Miller 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
PRODUCT CODE	ELC
PREDICATE DEVICES:	Sonendo GentleWave® System (K153157)

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 K153157.

Technical Characteristics:
The Sonendo GentleWave® System has similar physical and technical characteristics to the predicate device. The software controlled user interface has been modified to allow for clinician-determined treatment fluid concentrations with the default fluid concentration setting identical to the concentrations for the predicate K153157 with three setting options to decrease the concentration of the fluids.

Technical Characteristics	Sonendo GentleWave® System (modified)	Sonendo GentleWave® System (K153157)
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	Fixed

Each of the technical attributes are present in the predicate device. The modification to use treatment fluids at lower concentrations does not affect the substantial equivalent nature of the modified device, as this change merely allows for ability to select the treatment fluid concentration based on clinical evaluation of the treatment site. This change is consistent with traditional root canal procedures in that it enables the User to utilize treatment fluids with varying concentrations.

Performance Data:
Design control activities and risk analysis were performed in accordance with 21 CFR Part 820.30 and ISO14971:2007, respectively. Based on the changes being made and the risks associated with those changes, the following testing was determined to be necessary:

- Software validation in accordance with ANSI/AAMI/IEC 62304:2006, Medical device software – Software life cycle processes

Based on the results of this testing, the modified GentleWave System performs as intended and is substantially equivalent to the predicate device.

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.