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...
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

For 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
### Indications for Use

**E10(l) Number (if known)**

E181922

**Device Name**

Sonendo Material A

**Indications for Use (Describe)**

Permanent obturation of the root canal following root canal treatment.

**Type of Use (Select one or both, as applicable)**

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 931 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1980.

"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 70 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  
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Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASstaff@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."
7.0 510(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:**  July 17, 2018

**CONTACT PERSON:**  Eric Simon  
26061 Merit Circle, Suite 102  
Laguna Hills, CA 92653  
Phone: 949.766.3636  
Fax: 949.305.5201

**TRADE NAME:**  Sonendo Material A

**COMMON NAME:**  Resin, Root Canal Filling

**CLASSIFICATION NAME:**  Root canal filling resin

**DEVICE CLASSIFICATION:**  Class 2, per 21 CFR 872.3820

**REVIEWING PANEL:**  Dental

**ESTABLISHMENT REGISTRATION NO.:**  3010817521

**PRODUCT CODE:**  KIF

**PREDICATE DEVICES:**  iRoot SP Root Canal Sealer (K080917)

**Substantially Equivalent To:**
The Sonendo Material A is substantially equivalent in intended use, principle of operation and technological characteristics to the iRoot SP Root Canal Sealer (K080917).

**Description of the Device Subject to Premarket Notification:**
Sonendo Material A is a single component injectable paste material intended for permanent obturation of the root canal following root canal treatment. The device is comprised of alginate and a calcium containing compound which crosslinks in the presence of water to form an insoluble polymer. The placement into the root canal can be accomplished with or without the use a root canal point. The material is radiopaque and has physical properties such that it is suitable for root canal obturation. The material is packaged in either a syringe with single use dispensing tips or in a single dose capsule.
**Indication for Use:**
Permanent obturation of the root canal following root canal treatment.

**Device Comparison Table:**

<table>
<thead>
<tr>
<th></th>
<th>Sonendo Material A (Subject Device)</th>
<th>iRoot SP Root Canal Sealer (Predicate Device – K080917)</th>
<th>Discussion/Justification of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indication for Use</strong></td>
<td>Permanent obturation of the root canal following root canal treatment</td>
<td>Permanent obturation of the root canal following vital pulp-extirpation Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings</td>
<td>Equivalent</td>
</tr>
<tr>
<td><strong>Basic Chemical Composition</strong></td>
<td>Sodium alginate, glycerol, calcium sulfate, calcium tungstate, sodium pyrophosphate, polysorbate 60, zinc oxide, fumed silica, ytterbium fluoride, barium borosilicate</td>
<td>Zirconium oxide, dicalcium silicate, calcium hydroxide, calcium phosphate monobasic, filler, thickening agent</td>
<td>iRoot SP Root Canal Sealer was identified as the predicate device due to the subject device having similar materials and delivery form (i.e. premixed ready-to-use injectable paste) to the predicate. The predicate device is composed of lubricants, a radiopaque agent and thickening agents as does the subject device. Results of bench and biocompatibility testing completed in alignment with ISO 6876 and ISO 10993-1, respectively demonstrate that any material differences between the subject device and predicate device do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that Sonendo Material A is substantially equivalent to the predicate device.</td>
</tr>
<tr>
<td><strong>Standard</strong></td>
<td>ISO 6876 ISO 10993-1</td>
<td>ISO 6876 ISO 10993-1</td>
<td>Equivalent</td>
</tr>
<tr>
<td><strong>Treatment Site</strong></td>
<td>Root canal</td>
<td>Root Canal</td>
<td>Equivalent</td>
</tr>
<tr>
<td><strong>Sterile</strong></td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Equivalent</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Pre-loaded syringe</td>
<td>Pre-loaded syringe</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>

**Performance Data:**
Sonendo Material A has undergone extensive bench testing to provide evidence that its physical-chemical properties are substantially equivalent to iRoot SP Root Canal Sealer. Bench tests include: flow, working time, setting time, film thickness, solubility, and radiopacity in alignment with ISO 6876.
Biocompatibility test results demonstrate that Sonendo Material A is non-mutagenic, non-cytotoxic, does not cause an allergenic potential after multiple uses and has a good tolerance by subcutaneous tissue.

**Conclusion:**
Sonendo Material A and its predicate device have the same intended use, provides similar chemical, physical and biocompatible properties, and comparable performance specifications to iRoot SP Root Canal Sealer. The subject and predicate devices are packaged in similar materials and utilize similar methods of application. Any differences in the technological characteristics do not raise new issues of safety or effectiveness.