August 27, 2021

Sonendo, Inc.
Steve Ziemba
Vice President, Regulatory Affairs & Quality Assurance
26061 Merit Circle, Suite 102
Laguna Hills, California 92653

Re: K211995
Trade/Device Name: Sonendo Filling Material 5C
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: June 24, 2021
Received: June 28, 2021

Dear Steve Ziemba:

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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211995

Device Name
Sonendo Filling Material 5C

Indications for Use *(Describe)*
Sonendo Filling Material 5C is intended for permanent obturation of the root canal following root canal treatment.

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 K211995

1. Submitter:

Sonendo, Inc.
26061 Merit Circle, Suite 102
Laguna Hills, California 92653

Contact Person: Steven L. Ziémba
Telephone Number: (949) 667-8151
Fax Number: (949) 305-5201

Date Prepared: June 24, 2021

2. Device:

Name of Device: Sonendo Filling Material 5C
Common Name: Root Canal Filling Resin
Classification Name: Root Canal Filling Resin, per 21 CFR § 872.3820
Device Class: II
Product Code: KIF

3. Predicate Device:

Primary Predicate: *EndoREZ Dual Cure,* Ultradent Products, Inc., K071106, Product Code KIF

Reference Device: *Pulp Canal Sealer EWT,* Sybron Dental Specialties, Inc., K152956, Product Code KIF

4. Device Description

The **Sonendo Filling Material 5C** is a two-part filling material developed for permanent root canal filling. It is a water-soluble acrylate which is radiopaque and hardens with a chemical curing system. The **Sonendo Filling Material 5C** is packaged in plastic syringes with a syringe mixer and a dispensing tip. The syringe and dispensing tips are the only patient contacting devices packaged with the **Sonendo Filling Material 5C** and are commercially available.

5. Statement of Intended Use:

The **Sonendo Filling Material 5C** is intended for permanent obturation of the root canal following root canal treatment.

6. Summary of Technological Characteristics with the Predicate Device

The technological characteristics of the subject **Sonendo Filling Material 5C** are similar to the predicate device, EndoREZ Dual Cure (K071106). There are no substantial technical or functional differences between the **Sonendo Filling Material 5C** and the predicate device in

terms of chemical composition, function and intended use. Both are root canal filling resins consisting of a catalyst and base packaged in individual syringes. See Table 1 below for technological characteristics and comparisons of the root canal filling resins.

Table 1: Comparison of Subject and Predicate Devices

Element	***Sonendo Filling Material 5C (Subject Device)***	**EndoREZ Dual Cure (Predicate Device)**	**Comparison**
Company	Sonendo, Inc.	Ultradent Products, Inc.	N/A
510(k)	K211995	K071106	N/A
Indications for Use	The Sonendo Filling Material 5C is intended for permanent obturation of the root canal following root canal treatment.	EndoRez is designed to be used with EndoREZ Points and/or gutta percha for the filling of cleaned and shaped root canals. EndoREZ, in conjunction with a master cone and accessory cones (as needed), provides optimum sealing. Although EndoREZ Points are recommended, EndoREZ may be used with all conventional endodontic obturation techniques.	Indicated for same purpose - filling of root canals.
Target Users	Dental Professionals trained in endodontics.	Dental Professionals trained in endodontics.	Same
Basic Chemical Composition	Poly(ethylene glycol) diacrylate, water, 5-acrylamido-2,4,6-triiodoisophthalic acid, triethanolamine, sodium hydroxide, potassium persulfate	Diurethane dimethacrylate, triethylene glycol dimethacrylate, organophosphine oxide, benzoyl peroxide, radiopaque agent	Similar - The predicate device employs acrylate monomers catalyzed by a peroxide as does the subject device.
Material Compatibility	Biocompatibility profile is similar to currently marketed reference dental filling material and demonstrates no increased risk with respect to long-term biological safety.	Meets Biocompatibility Requirements of ISO 10993-1	Same

Element	*Sonendo Filling Material 5C (Subject Device)*	EndoREZ Dual Cure (Predicate Device)	Comparison
Flow (ISO 6876: 2012)	33.45 mm **≥ *17mm***	17.31 mm **≥ *17mm***	Same - Passed ISO 6876 test requirements
Working Time (ISO 6876: 2012)	32.98 mm **≥ *17mm***	17.38 mm **≥ *17mm***	Same - Passed ISO 6876 test requirements
Setting Time (ISO 6876: 2012)	60 minutes, 7 seconds **Claim of 1 - 24 hours** **Between 1 - 24 hours**	25 minutes, 46 seconds **Claim of 30 minutes** **No more than 10% longer**	Same - Passed ISO 6876 test requirements
Film Thickness (ISO 6876: 2012)	5 µm **≤ 50 µm**	5 µm **≤ 50 µm**	Same - Passed ISO 6876 test requirements
Solubility & Disintegration (ISO 6876:2012)	2.03% No disintegration **≤ 3.0% by mass** **No Disintegration**	.77% No disintegration **≤ 3.0% by mass** **No Disintegration**	Same - Passed ISO 6876 test requirements
Radio-opacity (ISO 6876:2012)	3.10 mm Al **≥ 3 mm of Aluminum**	6.6 mm Al **≥ 3 mm of Aluminum**	Same - Passed ISO 6876 test requirements

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the **Sonendo Filling Material 5C** was conducted in accordance with ISO 7405:2018 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, Annex A*, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process” as recognized by FDA. The biocompatibility testing included the following tests:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous Reactivity

4. Acute Systemic Toxicity
5. Subacute Toxicity
6. Genotoxicity
7. Intramuscular Implantation
8. Material mediated pyrogenicity

The biocompatibility testing conducted demonstrates adequate biocompatibility for the **Sonendo Filling Material 5C**.

ISO 6876 Testing

Testing according to ISO 6876:2012 *Dentistry - Root canal sealing materials* was performed on the **Sonendo Filling Material 5C** and as compared to the predicate device, it was substantially equivalent to the device and met the physical/mechanical properties of the standard.

Clinical Studies

No human clinical testing was conducted to support substantial equivalence.

8. Conclusion as to Substantial Equivalence

The similarities in chemical composition, function and intended use of the **Sonendo Filling Material 5C** with the legally marketed predicate device, EndoREZ Dual Cure (K071106), support substantial equivalence.