

K211995 Sonendo Filling Material 5CAug 27, 2021
60 days to decisionK211995 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k211995/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Root Canal Filling (KIF) |
| Date received | Jun 28, 2021 |
| Decision date | Aug 27, 2021 |
| Days to decision | 60 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sonendo, Inc. |
| Location | Laguna Hills, CA, US |
| Contact | Steve Ziemba |
| 510(k) history | 9 submissions · 9 cleared · 2013-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211995/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026