

K172460 ADHEAR SystemApr 27, 2018
256 days to decisionK172460 · Product code: **LXB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k172460/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hearing Aid, Bone Conduction (LXB) |
| Date received | Aug 14, 2017 |
| Decision date | Apr 27, 2018 |
| Days to decision | 256 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Med-EI Elektromedizinische Geraete GmbH |
| Location | Innsbruck, AT |
| Contact | Elizabeth Gfoeller |
| 510(k) history | 6 submissions · 5 cleared · 2018-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172460/> 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 June 28, 2026