

K914477 AUDIOTONE MODEL A-95 BEHIND-THE-EAR HEARING AIDOct 21, 1991
13 days to decisionK914477 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k914477/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received | Oct 8, 1991 |
| Decision date | Oct 21, 1991 |
| Days to decision | 13 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Miracle-Ear, Inc. |
| Location | Golden Valley, MN, US |
| Contact | KEVIN L KUTINA |
| 510(k) history | 65 submissions · 65 cleared · 1990-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914477/>. 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 July 5, 2026