

K954038 K-AMP 16, HI-BAND K-AMP, ULTRA COMPRESSION & HEARING PROTECTION/HEARING INSTRUMENT

Sep 18, 1995
21 days to decision

K954038 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k954038/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received | Aug 28, 1995 |
| Decision date | Sep 18, 1995 |
| Days to decision | 21 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Argosy Electronics |
| Location | Eden Prairie, MN, US |
| Contact | DAVID A PREVES |
| 510(k) history | 24 submissions · 24 cleared · 1993-1998 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k954038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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