

K964794 DAHLBERG K-AMP BTEDec 23, 1996
24 days to decisionK964794 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k964794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Nov 29, 1996
Decision date	Dec 23, 1996
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964794/> 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