

K953054 AM 260 OHMAug 15, 1995
46 days to decisionK953054 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k953054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jun 30, 1995
Decision date	Aug 15, 1995
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Electone, Inc.
Location	Mchenry, IL, US
Contact	JIM NEE
510(k) history	73 submissions · 73 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953054/> 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 4, 2026