

K802963 101, 151, 161 PORTABLE AUDIOMETERSDec 19, 1980
28 days to decisionK802963 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k802963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Nov 21, 1980
Decision date	Dec 19, 1980
Days to decision	28 days
Third-party review	No

APPLICANT

Company	Amplaid USA, Inc.
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1978-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k802963/> 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 1, 2026