

K971032 DANAVOX MODELS 163/162 BTEJun 17, 1997
88 days to decisionK971032 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k971032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Mar 21, 1997
Decision date	Jun 17, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gn Danavox, Inc.
Location	Eden Prairie, MN, US
Contact	WAYNE MORRIS
510(k) history	10 submissions · 10 cleared · 1986-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971032/> 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