

K812937 BEHIND-THE-EAR MODEL 115Nov 6, 1981
17 days to decisionK812937 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k812937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Oct 20, 1981
Decision date	Nov 6, 1981
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Danavox, Inc.
Location	Mchenry, IL, US
510(k) history	26 submissions · 26 cleared · 1977-1994

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Device record: <https://www.510kdatabase.net/k812937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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