FDA 510(k) Premarket Notification

K812938 IN-THE-EAR MODEL 821

CLEARED

Nov 6, 1981
17 days to decision

K812938 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k812938/

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