FDA 510(k) Premarket Notification

K905692 143 SERIES BTE

CLEARED

Jan 28, 1991
40 days to decision

K905692 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k905692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 19, 1990
Decision date	Jan 28, 1991
Days to decision	40 days
Third-party review	No

APPLICANT

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