FDA 510(k) Premarket Notification

K972106 PHONAK NOVO FORTE E3

CLEARED

Aug 15, 1997
71 days to decision

K972106 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k972106/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jun 5, 1997
Decision date	Aug 15, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Phonak, Inc.**
Location	Naperville, IL, US
Contact	LAURA M VOLL
510(k) history	37 submissions · 37 cleared · 1990-1997