FDA 510(k) Premarket Notification

K970215 AUDALLION II HEARING SYSTEM

CLEARED

Mar 31, 1997
69 days to decision

K970215 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k970215/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jan 21, 1997
Decision date	Mar 31, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Resound Corp.**
Location	Redwood City, CA, US
Contact	KRISTA M BUCKLES
510(k) history	41 submissions · 41 cleared · 1989-1999