

K970215 AUDALLION II HEARING SYSTEMMar 31, 1997
69 days to decisionK970215 · Product code: **ESD** · Ear, Nose, ThroatSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970215/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026