

K915711 IN THE EAR HEARING AIDJun 10, 1992
188 days to decisionK915711 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k915711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 5, 1991
Decision date	Jun 10, 1992
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Zenith-Omni H.C., Inc.
Location	New Haven, CT, US
Contact	RICHARD E MCMAHON
510(k) history	1 submissions · 1 cleared · 1992-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915711/> 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 6, 2026