

**K915450 IN THE EAR HEARING AID**Feb 27, 1992  
84 days to decisionK915450 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k915450/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 5, 1991
Decision date	Feb 27, 1992
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Zenith/Omni Hearing Instruments, Inc.</b>
Location	New Haven, CT, US
Contact	RICHARD MCMAHON
510(k) history	1 submissions · 1 cleared · 1992-1992

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915450/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 6, 2026