

**K943960 UV CURED METHYL METHACRYLATE HEARING AID  
SHELL MATERIALS**Oct 20, 1994  
66 days to decisionK943960 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k943960/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Aug 15, 1994
Decision date	Oct 20, 1994
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Miracle-Ear, Inc.</b>
Location	Golden Valley, MN, US
Contact	MELANIE RASKA
510(k) history	65 submissions · 65 cleared · 1990-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943960/> 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 5, 2026