

K941295 SHARP II HELIX HEARING AIDJun 17, 1994
92 days to decisionK941295 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k941295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Mar 17, 1994
Decision date	Jun 17, 1994
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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