

K001058 AUDIOSCREENER OAE + ABRJun 2, 2000
60 days to decisionK001058 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k001058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Apr 3, 2000
Decision date	Jun 2, 2000
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kedly, Inc.
Location	St. Louis, MO, US
Contact	RANDALL J KROHN
510(k) history	2 submissions · 2 cleared · 2000-2000

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