

**K921085 PROGRAMMED AUDIOMETRIC DEVICE  
(PAD)/RECORDS (PAR)**May 15, 1992  
70 days to decisionK921085 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k921085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Mar 6, 1992
Decision date	May 15, 1992
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hear-Well Technologies, Inc.</b>
Location	Guelph, CA
Contact	WAYNE GATEHOUSE
510(k) history	1 submissions · 1 cleared · 1992-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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