

**K953684 GSI 61 CLINICAL AUDIOMETER**Oct 27, 1995  
85 days to decisionK953684 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k953684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Aug 3, 1995
Decision date	Oct 27, 1995
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Grason-Stadler, Inc.</b>
Location	Mchenry, IL, US
Contact	JANICE E PAINTER
510(k) history	16 submissions · 16 cleared · 1979-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953684/> 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 May 30, 2026