

**K844997 IAI PROGRAM-COMPUTER PROGRAM**Apr 9, 1985  
104 days to decisionK844997 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k844997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Dec 26, 1984
Decision date	Apr 9, 1985
Days to decision	104 days
Third-party review	No

**APPLICANT**

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Company	<b>Intl. Acoustics, Inc.</b>
Location	Palatine, IL, US
Contact	GERALD A KIEN
510(k) history	5 submissions · 5 cleared · 1985-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k844997/>; 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 July 7, 2026