

**K050510 ECHOVIEW/SHIMASONIC DIAGNOSTIC ULTRASOUND  
SYSTEM, MODEL SDU-1100**Apr 1, 2005  
31 days to decisionK050510 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k050510/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 1, 2005
Decision date	Apr 1, 2005
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shimadzu Medical Systems</b>
Location	Gardena, CA, US
Contact	RANDAL WALKER
510(k) history	90 submissions · 90 cleared · 1989-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050510/> 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 18, 2026