

**K052500 DAR-8000F**Oct 17, 2005  
34 days to decisionK052500 · Product code: **IZI** · Radiology  
Source: <https://www.510kdatabase.net/k052500/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 13, 2005
Decision date	Oct 17, 2005
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

**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/k052500/> 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