

K052076 DAR-8000ISep 2, 2005
32 days to decisionK052076 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k052076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Angiographic (IZI)
Date received	Aug 1, 2005
Decision date	Sep 2, 2005
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052076/> Data sourced from FDA 510(k) public records (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. - Generated May 18, 2026