

**K941917 FLUOROPLUA CARDIAC AND/OR INSTAVIEW**Feb 24, 1995  
311 days to decisionK941917 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k941917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Apr 19, 1994
Decision date	Feb 24, 1995
Days to decision	311 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fidelity Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	RONEN GANS
510(k) history	8 submissions · 8 cleared · 1984-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941917/> 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 19, 2026