

**K864584 FLUOROVISION CONTRAST ENHANCER**Dec 29, 1986  
39 days to decisionK864584 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k864584/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Nov 20, 1986
Decision date	Dec 29, 1986
Days to decision	39 days
Third-party review	No

**APPLICANT**

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Company	<b>Digivision, Inc.</b>
Location	North Attleboro, MA, US
Contact	JAMES R VEALE
510(k) history	4 submissions · 4 cleared · 1986-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864584/>; 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 20, 2026