

**K913012 DIGITAL FLUORO STORE(DFS) W/NUMERICAL SUFFIXES**Sep 23, 1991  
77 days to decisionK913012 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k913012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jul 8, 1991
Decision date	Sep 23, 1991
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Eigen</b>
Location	Nevada City, CA, US
Contact	MARK A HOFFMAN
510(k) history	16 submissions · 16 cleared · 1988-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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