

**K943821 KYOKKO SPEC-SERIES INTENSIFY SCREENS-SPEC,SUPER SPEC**Aug 22, 1994  
68 days to decisionK943821 · Product code: **EAM** · Radiology  
Source: <https://www.510kdatabase.net/k943821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Intensifying, Radiographic (EAM)
Date received	Jun 15, 1994
Decision date	Aug 22, 1994
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical System U.S.A., Inc.</b>
Location	Stamford, CT, US
Contact	ROBERT A UZENOFF
510(k) history	71 submissions · 71 cleared · 1988-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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