

K943822 FUJI UM MAMMO SERIES INTENSIFY SCREENS:Aug 22, 1994
68 days to decisionK943822 · Product code: **EAM** · Radiology
Source: <https://www.510kdatabase.net/k943822/>**SUBMISSION DETAILS**

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

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

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