FDA 510(k) Premarket Notification

K943821 KYOKKO SPEC-SERIES INTENSIFY SCREENS-SPEC,SUPER SPEC

CLEARED

Aug 22, 1994
68 days to decision

K943821 · Product code: **EAM** · Radiology
Source: https://www.510kdatabase.net/k943821/

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