FDA 510(k) Premarket Notification

K942399 KYOKKO UM SERIES INTENSIFYING SCREEN

CLEARED

Jun 10, 1994
22 days to decision

K942399 · Product code: **EAM** · Radiology
Source: https://www.510kdatabase.net/k942399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Intensifying, Radiographic (EAM)
Date received	May 19, 1994
Decision date	Jun 10, 1994
Days to decision	22 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