FDA 510(k) Premarket Notification

K111646 ASPIRE CR FOR MAMMOGRAPHY SYSTEM (CRM)

CLEARED

Dec 8, 2011
178 days to decision

K111646 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k111646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jun 13, 2011
Decision date	Dec 8, 2011
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary
Other names	FCR ASPIRE CRN (READER). NOTE FOR GENERAL RADIOGRAPHY, READER IS CARBON XL2/FCR

APPLICANT

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