

**K111646 ASPIRE CR FOR MAMMOGRAPHY SYSTEM (CRM)**Dec 8, 2011  
178 days to decisionK111646 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k111646/>**SUBMISSION DETAILS**

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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**

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Company	<b>Fujifilm Medical System U.S.A., Inc.</b>
Location	Stamford, CT, US
Contact	DEBBIE PEACOCK
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/k111646/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026