

K121674 ASPIRE HD PLUS, ASPIRE HD-SSep 21, 2012
107 days to decisionK121674 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k121674/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jun 6, 2012
Decision date	Sep 21, 2012
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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