

**K173132 ASPIRE Cristalle**Oct 27, 2017  
28 days to decisionK173132 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k173132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Sep 29, 2017
Decision date	Oct 27, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Location	Stamford, CT, US
Contact	Jyh-Shyan Lin
510(k) history	39 submissions · 39 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173132/> 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