

K212873 Aspire CristalleMay 27, 2022
260 days to decisionK212873 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k212873/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Sep 9, 2021
Decision date	May 27, 2022
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Fujifilm Medical Systems U.S.A., Inc.
Contact	Jeffrey Wan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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