

K220295 ARIETTA 50Apr 29, 2022
86 days to decisionK220295 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k220295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 2, 2022
Decision date	Apr 29, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Healthcare Corporation
Location	Kashiwa-Shi, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	FUJIFILM Healthcare Americas Corporation
Contact	Dennis Domoracki

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

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