

K231941 ARIETTA x10Nov 20, 2023
143 days to decisionK231941 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k231941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 30, 2023
Decision date	Nov 20, 2023
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Healthcare Americas Corporation
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025

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