FDA 510(k) Premarket Notification

K220295 ARIETTA 50

CLEARED

Apr 29, 2022
86 days to decision

K220295 · 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