FDA 510(k) Premarket Notification

K254021 Accuro XV

CLEARED

Apr 9, 2026
114 days to decision

K254021 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k254021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 16, 2025
Decision date	Apr 9, 2026
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rivanna Medical, Inc.**
Location	Charlottesville, VA, US
Contact	F. William Mauldin
Website	https://rivannamedical.com
510(k) history	3 submissions · 3 cleared · 2025-2026

Rivanna Medical, Inc. develops AI-powered clinical decision-support platforms for Radiology imaging and procedural guidance. The company is headquartered in Charlottesville, Virginia, with an FDA-registered, ISO 13485:2016-certified manufacturing facility. Rivanna's proprietary technology automates complex anatomical analysis at the point of care, enabling faster clinical decisions while reducing operator variability. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. First clearance was in 2025, and t...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k254021/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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