

K243937 Accuro 3SMay 23, 2025
154 days to decisionK243937 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k243937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 20, 2024
Decision date	May 23, 2025
Days to decision	154 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...