

**K250469 Accuro® 3S Needle Guide Kit**Jun 13, 2025  
115 days to decisionK250469 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k250469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Feb 18, 2025
Decision date	Jun 13, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rivanna Medical, Inc.</b>
Location	Charlottesville, VA, US
Contact	Will Mauldin
Website	<a href="https://rivannamedical.com">https://rivannamedical.com</a>
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...