

**K252361 AccurECG Analysis System (v2.0)**Dec 22, 2025  
146 days to decisionK252361 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 29, 2025
Decision date	Dec 22, 2025
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Accurkardia, Inc.</b>
Location	New York, NY, US
Contact	Juan Jimenez
510(k) history	2 submissions · 2 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medtech Impact Partners</b>
Contact	Kwame Ulmer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252361/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026