FDA 510(k) Premarket Notification

CLEARED

K252361 AccurECG Analysis System (v2.0)

Dec 22, 2025
146 days to decision

K252361 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k252361/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Medtech Impact Partners**
Contact	Kwame Ulmer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov