FDA 510(k) Premarket Notification

K223013 AccurECG Analysis System

CLEARED

Jun 23, 2023
267 days to decision

K223013 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k223013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 29, 2022
Decision date	Jun 23, 2023
Days to decision	267 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 C. Jimenez
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Kwame Ulmer

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