

K252978 ScioCardio ECG Analysis Platform

Jul 9, 2026
295 days to decision

K252978 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k252978/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 17, 2025
Decision date	Jul 9, 2026
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synergen Technology Labs, LLC
Location	Dallas, TX, US
Contact	Sunil Konda
510(k) history	2 submissions · 2 cleared · 2018-2026