

K253141 DeepRhythmAIDec 11, 2025
77 days to decisionK253141 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k253141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 25, 2025
Decision date	Dec 11, 2025
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicalgorithmics S.A.
Location	New York, NY, US
Contact	Agnieszka Romowicz
510(k) history	11 submissions · 11 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253141/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026