

**K250932 DeepRhythmAI**May 27, 2025  
60 days to decisionK250932 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k250932/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 28, 2025
Decision date	May 27, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250932/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026