

**K210822 DeepRhythmAI**Jul 27, 2022  
495 days to decisionK210822 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210822/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 19, 2021
Decision date	Jul 27, 2022
Days to decision	495 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	Marek Dziubinski
510(k) history	11 submissions · 11 cleared · 2012-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medicalgorithmics US Holding Corporation</b>
Contact	Agnieszka Romowicz

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210822/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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