

K232161 DeepRhythm PlatformJun 20, 2024
336 days to decisionK232161 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k232161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 20, 2023
Decision date	Jun 20, 2024
Days to decision	336 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	Maciej Gamrot
510(k) history	11 submissions · 11 cleared · 2012-2025

REGULATORY CONSULTANT

Consulting firm	Medicalgorithmics US Holding Corporation
Contact	Joanna Dabala

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232161/> 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