

**K193104 Unified Arrhythmia Diagnostic System PocketECG IV**Apr 9, 2020  
153 days to decisionK193104 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193104/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Nov 8, 2019
Decision date	Apr 9, 2020
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193104/> 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 24, 2026