

**K223049 CardioSTAT® ECG Test Solution**Mar 22, 2023  
174 days to decisionK223049 · Product code: **DSH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 29, 2022
Decision date	Mar 22, 2023
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icentia, Inc.</b>
Location	Quebec, CA
Contact	Danièle Grondines
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ultra Life Science Solutions, Inc.</b>
Contact	Christina Henza

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223049/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026