

K230265 MoMe® ARC Wireless Ambulatory ECG Monitoring and Detection SystemOct 6, 2023
248 days to decisionK230265 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k230265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jan 31, 2023
Decision date	Oct 6, 2023
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Infobionic, Inc.
Location	Lowell, MA, US
Contact	Dave MacCutcheon
510(k) history	5 submissions · 5 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	MethodSense, Inc.
Contact	Rita King

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/k230265/> 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 25, 2026