FDA 510(k) Premarket Notification

CLEARED

K250356 MoMe ARC® Wireless Ambulatory ECG Monitoring and Detection System (32000)

Jul 29, 2025
172 days to decision

K250356 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k250356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Feb 7, 2025
Decision date	Jul 29, 2025
Days to decision	172 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