

K231424 HeartBeam AIMIGo(TM) SystemDec 13, 2024
576 days to decisionK231424 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k231424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	May 17, 2023
Decision date	Dec 13, 2024
Days to decision	576 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heartbeam, Inc.
Location	Santa Clara, CA, US
Contact	Ken Persen
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Veranex, Inc.
Contact	Deborah Castillo

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/k231424/> 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