FDA 510(k) Premarket Notification

K231424 HeartBeam AIMIGo(TM) System

CLEARED

Dec 13, 2024
576 days to decision

K231424 · Product code: **MWJ** · Cardiovascular
Source: 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