CLEARED

K250258 HeartBeam AIMIGo with 12-L ECG Synthesis Software System

Dec 8, 2025
314 days to decision

K250258 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k250258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jan 28, 2025
Decision date	Dec 8, 2025
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT06123130

AIMIGo 12L ECG Synthesis Software Pivotal Study for Arrythmia Detection

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	198 patients (actual)
Study sites	5 sites
Condition studied	Arrhythmias, Cardiac; Atrial Fibrillation; Atrial Flutter; Bradycardia; Tachycardia
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 20, 2024
Sponsor	HeartBeam, Inc. (Industry)

Primary outcome

Clinical equivalence of ECG intervals compared between AIMIGo Synthesized 12L and reference standard 12L

Secondary outcome

Clinical diagnostic accuracy of AIMIGo Synthesized 12L compared with the reference standard 12L ECG for the classification of arrhythmia.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06123130