

**K250233 PreemptiveAI Clinical SDK**Feb 13, 2026  
382 days to decisionK250233 · Product code: **DXH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250233/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jan 27, 2025
Decision date	Feb 13, 2026
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Measure Labs, Inc. (Db a Preemptiveai, Inc.)</b>
Location	Seattle, WA, US
Contact	Matt Whitehill
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Matt Whitehill

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**CLINICAL EVIDENCE - NCT06696339****Assessment of Heart Rate Measurement Accuracy for the PreemptiveAI SDK in Adults**

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Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	100 patients (estimated)
Study sites	1 site
Condition studied	Heart Rate in the General Public
Study type	Observational
Completion date	Mar 1, 2025
Sponsor	PreemptiveAI, Inc (Industry)

**Primary outcome****Heart Rate Error**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT06696339](https://clinicaltrials.gov/study/NCT06696339)