

K252360 ECG-AI Pulmonary Hypertension (PH) 12-Lead algorithm (1020)Mar 28, 2026
242 days to decisionK252360 · Product code: **SAT** · Cardiovascular
Source: <https://www.510kdatabase.net/k252360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulmonary Hypertension Machine Learning-based Notification Software (SAT)
Date received	Jul 29, 2025
Decision date	Mar 28, 2026
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anumana, Inc.
Location	Cambridge, MA, US
Contact	Taylor Gold West
510(k) history	5 submissions · 5 cleared · 2023-2026

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