

K250652 ECG-AI Low Ejection Fraction (LEF) 12-Lead algorithm (1010)Jul 28, 2025
146 days to decisionK250652 · Product code: **QYE** · Cardiovascular
Source: <https://www.510kdatabase.net/k250652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced Ejection Fraction Machine Learning-based Notification Software (QYE)
Date received	Mar 4, 2025
Decision date	Jul 28, 2025
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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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