

K232699 Low Ejection Fraction AI-ECG AlgorithmSep 28, 2023
23 days to decisionK232699 · Product code: **QYE** · CardiovascularSource: <https://www.510kdatabase.net/k232699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced Ejection Fraction Machine Learning-based Notification Software (QYE)
Date received	Sep 5, 2023
Decision date	Sep 28, 2023
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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