

K233549 Tempus ECG-AFJun 21, 2024
231 days to decisionK233549 · Product code: **SBQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k233549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Atrial Fibrillation Risk Prediction Machine Learning-based Notification Software (SBQ)
Date received	Nov 3, 2023
Decision date	Jun 21, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tempus AI, Inc.
Location	Chicago, IL, US
Contact	Alain Silk
510(k) history	3 submissions · 3 cleared · 2024-2025

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