

**K250119 Tempus ECG-Low EF**Jul 15, 2025  
180 days to decisionK250119 · Product code: **QYE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250119/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced Ejection Fraction Machine Learning-based Notification Software (QYE)
Date received	Jan 16, 2025
Decision date	Jul 15, 2025
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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