

**K241868 xR IVD**Sep 19, 2025  
449 days to decisionK241868 · Product code: **PZM** · Pathology  
Source: <https://www.510kdatabase.net/k241868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Jun 27, 2024
Decision date	Sep 19, 2025
Days to decision	449 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	Sarah Piloto
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/k241868/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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