

TEMPUS

Tempus Receives U.S. FDA Special 510(k) Clearance for Updated Tempus Pixel Device

September 11, 2025

CHICAGO--(BUSINESS WIRE)--Sep. 11, 2025-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its updated Tempus Pixel, an AI-powered cardiac imaging platform. This update allows the generation of T1 and T2 inline maps, further enhancing the device's capabilities for cardiac MR image analysis.

Tempus Pixel provides advanced viewing and automated reporting of cardiac MR images, improving efficiency and accuracy in flow visualization, functional analysis, and tissue characterization. AI-enabled radiology, like Tempus Pixel, enhances medical imaging by rapidly analyzing scans, highlighting subtle abnormalities, and generating consistent, actionable insights. By improving accuracy and efficiency, it empowers clinicians to make faster, more informed decisions and deliver personalized patient care.

Unlike conventional MR images that show only brightness differences, T1 and T2 maps provide precise numerical values to cardiac tissue characteristics, helping clinicians detect conditions such as fibrosis, inflammation, or edema, that may otherwise go undetected. With its newly cleared functionality, Tempus Pixel can now generate T1 and T2 inline maps directly from raw MRI data, even when the scanner itself does not produce them, calculating values at every pixel across the image to create detailed DICOM maps for comprehensive tissue assessment.

"This marks another important regulatory milestone for Tempus and underscores our commitment to advancing AI-driven imaging technology that is both scientifically rigorous and clinically meaningful," said Chris Scotti DiVetta, Senior Vice President of AI Applications at Tempus. "With inline maps generated by Tempus Pixel, cardiologists and radiologists gain a comprehensive view of heart tissue, enabling deeper insights into cardiac health and helping them deliver more precise, personalized care to their patients."

Tempus has developed and deployed a suite of advanced algorithms across radiology and pathology, helping physicians deliver more precision, personalized care. Its strategic acquisitions have further strengthened its footprint in these fields. In 2022, Tempus acquired Arterys, incorporating its AI-powered tools for analyzing imaging data—ranging from lung CT scans and chest X-rays to cardiac MRIs—into Tempus' platform. Most recently, Tempus acquired Paige, an AI company specializing in digital pathology, bringing a proprietary dataset of almost 7 million clinically annotated, de-identified pathology slides to accelerate Tempus' efforts.

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of multimodal data, and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit tempus.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, about Tempus and Tempus' industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements, including, but not limited to, statements regarding the expected outcomes and benefits of Tempus Pixel and its capabilities for customers. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "going to," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Tempus cautions you that the foregoing may not include all of the forward-looking statements made in this press release.

You should not rely on forward-looking statements as predictions of future events. Tempus has based the forward-looking statements contained in this press release primarily on its current expectations and projections about future events and trends that it believes may affect Tempus' business, financial condition, results of operations and prospects. These forward-looking statements are subject to risks and uncertainties related to: Tempus' financial performance; the ability to attract and retain customers and partners; managing Tempus' growth and future expenses; competition and new market entrants; compliance with new laws, regulations and executive actions, including any evolving regulations in the artificial intelligence space; the ability to maintain, protect and enhance Tempus' intellectual property; the ability to attract and retain qualified team members and key personnel; the ability to repay or refinance outstanding debt, or to access additional financing; future acquisitions, divestitures or investments; the potential adverse impact of climate change, natural disasters, health epidemics, macroeconomic conditions, and war or other armed conflict, as well as risks, uncertainties, and other factors described in the section titled "Risk Factors" in Tempus' Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission ("SEC") on February 24, 2025, as well as in other filings Tempus may make with the SEC in the future. In addition, any forward-looking statements contained in this press release are based on assumptions that Tempus believes to be reasonable as of this date. Tempus undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this press release or to reflect new information or the occurrence of unanticipated events, except as required by law.

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