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Tempus Receives FDA Clearance for its ECG-MR AI Product Designed to Identify Undiagnosed Mitral Regurgitation

September 28, 2026

ECG-MR becomes the fourth FDA-cleared Tempus ECG-AI product, spanning arrhythmia, heart function, pulmonary vascular and valvular disease

CHICAGO--(BUSINESS WIRE)--Sep. 28, 2026-- Tempus AI, Inc. (NASDAQ: TEM) today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Tempus ECG-MR, an AI product that analyzes standard 12-lead resting electrocardiograms (ECGs) to detect signs associated with undiagnosed moderate or severe mitral regurgitation (MR).

MR is a common form of heart valve disease where blood leaks backward through the mitral valve. Because early stages are often asymptomatic or manifest as non-specific symptoms like shortness of breath, MR frequently remains undiagnosed until advanced stages. Tempus ECG-MR serves as an early detection tool to help identify high-risk patients who should be referred for further evaluation, such as follow-up diagnostic imaging.

"A standard ECG contains far more information than we have traditionally been able to use," said Brandon Fornwalt, MD, PhD, Senior Vice President of Cardiology at Tempus. "With the fourth FDA-cleared Tempus ECG-AI product, we're building a growing portfolio that can identify signals across numerous types of heart and vascular disease from the same ECG, helping provide clinicians with more actionable information from a test already embedded in everyday care."

Tempus ECG-MR

Tempus ECG-MR is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with having moderate or severe mitral regurgitation (MR). It is for use on clinical diagnostic ECG recordings collected at a healthcare facility from patients 65 years of age or older at risk of cardiovascular disease. Such cardiovascular risk factors include, but are not limited to, history of coronary artery disease, hypertension, obesity, or diabetes; or other signs or symptoms of heart disease, such as dyspnea, chest pain, or lower extremity edema. The device is indicated for patients without prior mitral valve intervention and without prior diagnosis of moderate or severe mitral regurgitation.

Tempus ECG-MR only analyzes ECG data and provides a binary output for interpretation. Tempus ECG-MR is not intended to be a stand-alone diagnostic tool for cardiac conditions, should not be used for serial patient monitoring, and should not be used on ECGs with paced rhythms. Results should be interpreted in conjunction with other diagnostic information, including the patient's original ECG recordings and other tests, as well as the patient's symptoms and clinical history.

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 ECG-MR 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, 2025, filed with the Securities and Exchange Commission ("SEC") on February 24, 2026, 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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