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Tempus Receives U.S. FDA 510(k) Clearance for Tempus ECG-Low EF Software

July 16, 2025

CHICAGO--(BUSINESS WIRE)--Jul. 16, 2025-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Tempus ECG-Low EF (ejection fraction) software, which uses AI to identify certain patients who may have a low left ventricular ejection fraction (LVEF).

Tempus ECG-Low EF joins [Tempus ECG-AF](#) as the second FDA-cleared ECG-AI device in Tempus' growing suite of next generation devices designed to identify patients at risk for a variety of cardiovascular conditions.

"With Tempus ECG-Low EF, we're adding another powerful tool to the hands of clinicians to help them identify patients at risk for serious cardiovascular conditions much earlier in their care journey," said Brandon Fornwalt, MD, PhD, Senior Vice President of Cardiology at Tempus. "Detection of LVEF is essential for undiagnosed patients, and this technology enables us to deliver that capability at scale to transform patient care. The addition of a second FDA-cleared Tempus ECG-AI solution reflects our continued commitment to advancing AI-driven cardiology."

Ejection fraction measures the percentage of blood that the heart pumps out with each beat. A reduced LVEF may indicate a range of serious cardiovascular conditions, including heart failure, cardiomyopathy, or damage from a prior heart attack. Tempus ECG-Low EF is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with having a low left ventricular ejection fraction (LVEF less than or equal to 40%). It is for use on clinical diagnostic ECG recordings collected at a healthcare facility from patients 40 years of age or older at risk of heart failure. This population includes but is not limited to patients with atrial fibrillation, aortic stenosis, cardiomyopathy, myocardial infarction, diabetes, hypertension, mitral regurgitation, and ischemic heart disease.

Tempus ECG-Low EF only analyzes ECG data and provides a binary output for interpretation. Tempus ECG-Low EF is not intended to be a stand-alone diagnostic tool for cardiac conditions, should not be used for 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. A positive result may suggest the need for further clinical evaluation in order to establish a diagnosis of low LVEF. Patients receiving a negative result should continue to be evaluated in accordance with current medical practice standards using all available clinical information.

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-Low EF 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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