Tempus Receives U.S. FDA 510(k) Clearance for Tempus ECG-AF, an AI-based Algorithm that Identifies Patients at Increased Risk of AFib

June 26, 2024

CHICAGO--(BUSINESS WIRE)--Jun. 26, 2024-- Tempus AI, Inc. (NASDAQ: TEM), a leader in artificial intelligence and precision medicine, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Tempus ECG-AF device that uses AI to help identify patients who may be at increased risk of atrial fibrillation/flutter (AF). This is the first FDA clearance for an AF indication in the category known as “cardiovascular machine learning-based notification software” and paves the way for physicians to use this innovative algorithm in the care of their patients.

AF, a common cause of stroke, affects millions of people and can be challenging to diagnose. This clearance solidifies Tempus’ innovative approach to offering physicians AI-based clinical solutions that support the potential for earlier identification of cardiovascular disease and conditions. ECG-AF is the first of a suite of next generation diagnostics that Tempus has designed to identify patients at risk for a variety of cardiovascular conditions.

“We believe that there are too many patients who die from AF-related causes unnecessarily due to underdiagnosis or undertreatment,” said Brandon Fornwalt, MD, PhD, Senior Vice President of Cardiology at Tempus. “The clearance of Tempus ECG-AF allows us to better support clinicians in potentially finding patients much earlier, when treatments can be more effective.”

The Tempus ECG-AF algorithm is intended for use to analyze recordings of 12-lead electrocardiogram (ECG) devices and detect signs associated with a patient experiencing AF within the next 12 months. It is for use on resting 12-lead ECG recordings collected at a healthcare facility from patients 65 years of age or older who do not have a known history of AF or other specified conditions. The device provides clinicians with results that 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. Tempus ECG-AF does not describe a person’s overall risk of experiencing AF and should not serve as the sole basis for diagnosis of AF. Results should not be used as the basis for treatment of AF and are not intended to rule out AF follow-up.

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 potential for Tempus’ ECG-AF device to support physicians and clinicians in finding patients who are at risk for cardiovascular disease and conditions earlier; the expected benefits of such earlier identification of patients; Tempus’ belief that patients at the risk of AF are underdiagnosed and undertreated; and AF-related patient population. 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: the intended use of Tempus’ products and services; 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’ Final Prospectus filed with the Securities and Exchange Commission (“SEC”) on June 17, 2024, pursuant to Rule 424(b)(4) under the Securities Act, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240626299737/en/

Tempus Communications
Erin Carron
media@tempus.com

Source: Tempus