FDA Grants Breakthrough Device Designation To Tempus' Atrial Fibrillation ECG Analysis Platform, Developed in Collaboration With Geisinger

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Tempus, a leader in artificial intelligence and precision medicine, today announced that the U.S. Food & Drug Administration (FDA) has granted the company Breakthrough Device Designation for its ECG Analysis Platform. The platform, developed in collaboration with Geisinger, aids clinicians in identifying patients at increased risk of developing atrial fibrillation (AFib) or atrial flutter. Breakthrough Designation entitles the platform to an expedited regulatory process.

The platform was designated as a Breakthrough Device for use with patients 40 years of age and older, without pre-existing or concurrent AFib or atrial flutter, and who are at elevated risk of stroke based on a commonly used clinical stroke risk assessment tool (i.e., CHA_2DS_2-VASc score of ≥4). The device analyzes the results of a 12-lead ECG administered as part of routine care to provide clinicians with insight into a patient's risk of future atrial fibrillation and/or atrial flutter events. When interpreted in conjunction with other available clinical information this can support clinicians in pursuing early and proactive diagnoses of AFib and atrial flutter with the goal of enabling improved clinical management of these conditions and their associated health risks.

AFib, which is a leading cause of stroke, is frequently unrecognized and untreated. Currently, there are no available devices to help physicians identify asymptomatic patients without a known history of cardiac arrhythmia who are at increased risk of future AFib, which carries other health risks including stroke and death. The Tempus ECG Analysis Platform is tackling that challenge by analyzing results of a widely-used clinical test, the 12-lead ECG, with software that identifies patients at increased risk of developing AFib or atrial flutter within the next 12 months.

A team of Geisinger and Tempus scientists and clinicians recently published a related study in *Circulation*, which showed that artificial intelligence can predict risk of new AFib and AFib-related stroke. For this research study, the combined team of data scientists and medical researchers used 1.6 million ECGs to train a deep neural network to predict, among people without a previous history of AFib, who would develop it within the next 12 months. In people with no history of AFib that went on to have an AFib-related stroke, nearly two thirds would have been predicted to be at high-risk before the stroke.

"In granting our request for Breakthrough Device designation, the FDA is helping bring the power of artificial intelligence to patients, with new, smarter tools that can support clinicians in predicting future clinical events," said Joel Dudley, Ph.D., Chief Scientific Officer of Tempus. "Every year, hundreds of millions of ECGs are performed in the U.S. to detect cardiac abnormalities as part of routine clinical care. We are making ECGs smarter so that they can also identify the risk of future clinical events of interest, such as AFib, thus enabling clinicians to act earlier in the course of disease and improve patient outcomes."

"Much of what we do as clinicians relies on predicting the future. Geisinger and Tempus are working together to make smarter, more accurate predictions about future clinical events," said Brandon Fornwalt, MD, Ph.D., Chair of Geisinger's Department of Translational Data Science and Informatics. "This is ultimately about helping patients and fulfilling the promise of precision health by supporting clinical decision making with additional patient-specific information, and we are excited that the FDA recognizes the importance of this work."

The FDA's Breakthrough Device Program was established to accelerate the availability of transformative medical devices to patients and healthcare providers by speeding up their development, assessment and review, while preserving the statutory standards for premarket review and authorization. Designation is awarded to innovative devices that provide more effective diagnosis or treatment of life-threatening conditions and that offer significant advantages over the existing standard of care, where no approved or cleared alternatives exist, and where early device availability is in patients' best interests.

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 clinical and molecular data, and an operating system to make that data accessible and useful, Tempus enables physicians to make real-time, data-driven decisions 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.

About Geisinger

Geisinger is committed to making better health easier for the more than 1 million people it serves. Founded more than 100 years ago by Abigail Geisinger, the system now includes nine hospital campuses, a 550,000-member health plan, a Research Institute and the Geisinger Commonwealth School of Medicine. With nearly 24,000 employees and more than 1,600 employed physicians, Geisinger boosts its hometown economies in Pennsylvania by billions of dollars annually. Learn more at geisinger.org or connect with us on Facebook, Instagram, LinkedIn and Twitter.