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# HeartBeam Announces FDA Clearance for At-Home, High-Fidelity Heart Monitoring Technology

- *First cable-free, ambulatory ECG that captures the heart's electrical signals from three distinct directions for high-fidelity data collection and advanced diagnostics*
- *Patients can have the credit card-sized device with them at all times, ready to record an ECG whenever they feel symptoms and reduce delays in care*
- *Company to initiate Early Access Program to gain important patient and physician feedback on the use of the system in preparation for commercial launch*

SANTA CLARA, Calif.--(BUSINESS WIRE)-- **HeartBeam, Inc.** (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful cardiac insights, today announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance of the HeartBeam system for comprehensive arrhythmia assessment. With its patented design, the HeartBeam device is the first-of-its-kind to receive FDA clearance. As a high-fidelity electrocardiogram (ECG) system with a credit card-sized form factor and cable-free design, it captures heart signals from three distinct directions for actionable heart health information.

When a patient feels symptoms, the HeartBeam patient app guides them through the process of placing the device on their chest and capturing a 30-second recording. Once a recording is taken, the signals are sent to the cloud, processed and sent to a physician for review. The physician reviews the ECG recording in the context of the patient's symptoms and medical history, then follows up with the patient on next steps. The Company plans to initiate an Early Access Program and is creating a waitlist of interested patients and physicians.

**To Join the Waitlist, Sign Up Here**

**Watch a Video of How the HeartBeam System Works**

"It's well documented that patients who delay seeking care for their cardiac symptoms face worse clinical outcomes. The ability for patients to capture high-fidelity ECG signals from three directions wherever they are when symptoms occur will help patients get the care they need in a timelier manner," said Robert Eno, Chief Executive Officer, HeartBeam. "The FDA clearance of our technology is a significant milestone for the Company that brings us one step closer to fulfilling our vision of providing unprecedented cardiac insights to individuals and physicians."

The FDA clearance is foundational and will serve as the basis for future submissions as the Company strives to simplify the access of intelligent and actionable 12-lead ECGs for both patients and physicians. Future planned advances include:

- **Synthesized 12-lead ECG:** The HeartBeam system is designed to be capable of synthesizing the heart's signals collected from three directions into a 12-lead ECG using a personalized transformation matrix as demonstrated in this pilot study.
- **AI-Based Classification Algorithms:** Data presented earlier this year demonstrated that HeartBeam's deep learning algorithm has the potential to greatly improve the detection of atrial flutter, even outperforming cardiologists in detecting some arrhythmias.
- **Heart Attack Detection:** A study published in *JACC: Advances* showed that HeartBeam's ambulatory technology is comparable to a standard 12-lead ECG in identifying coronary occlusions and is highly accurate (Area Under the Curve of 95%). Another feasibility study highlighted the potential of HeartBeam's technology to calculate a heart attack risk-score to assess chest pain remotely.

HeartBeam's proprietary technology has the potential to unlock valuable diagnostic and predictive insights. The ease of collecting higher-fidelity ECG signals will enable patients to gather a series of recordings over time. The Company aims to leverage AI to analyze this rich set of data, delivering a longitudinal view of a patient's cardiac health and predicting cardiac conditions before symptoms appear. HeartBeam believes its groundbreaking technology presents a transformative opportunity to bring about a paradigm shift in cardiovascular care for millions of patients globally.

**About HeartBeam, Inc.**

HeartBeam, Inc. (NASDAQ: BEAT) is a medical technology company dedicated to transforming the detection and monitoring of critical cardiac conditions. The Company is creating the first ever cable-free synthesized 12-lead ECG capable of capturing the heart's electrical signals from three distinct directions. This platform technology is designed for portable devices that can be used wherever the patient is to deliver actionable heart intelligence. Physicians will be able to identify cardiac health trends and acute conditions and direct patients to the appropriate care – all outside of a medical facility, thus redefining the future of cardiac health management. The Company holds 13 US and 4 international issued patents related to technology enablement. For additional information, visit HeartBeam.com.

**About the HeartBeam System**

The HeartBeam System is a portable non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional. For full safety information, see the full **Instructions for Use** or **Clinician Portal Manual.**

**Forward-Looking Statements**

All statements in this release that are not based on historical fact are "forward-looking statements." While management has based any forward-looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which

could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Forms 10-K, 10-Q and other reports filed with the SEC and available at www.sec.gov. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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