December 10, 2025

HeartBeam Receives FDA Clearance for First-Ever, Cable-Free Synthesized 12-Lead ECG for At-Home Arrhythmia Assessment

- *FDA Clearance Granted After Successful Appeal, Overturning Prior Not Substantially Equivalent (NSE) Outcome*
- *HeartBeam's Credit-Card Sized Device Delivers Clinical-Grade Insights Directly to Patients Anytime, Anywhere*
- *Pivotal Milestone Unlocks Multiple Key Initiatives in Company's Growth Strategy*

SANTA CLARA, Calif.--(BUSINESS WIRE)--

HeartBeam, Inc. (NASDAQ: BEAT), a medical technology company focused on transforming cardiac care by providing powerful personalized insights, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the Company's groundbreaking 12-lead electrocardiogram (ECG) synthesis software for the assessment of arrhythmias. This clearance follows HeartBeam's successful appeal of a prior Not Substantially Equivalent (NSE) determination.

Unlike any single-lead or 6-lead consumer device, HeartBeam's patented cable-free technology captures the heart's electrical signals in three non-coplanar dimensions and synthesizes them into a 12-lead ECG representation. This allows patients to obtain an ECG reading for their arrhythmia from the comfort of home, or wherever they happen to be, representing a new level of convenience and peace of mind. The synthesized 12-lead ECG is promptly reviewed by an on-demand, board-certified cardiologist.

With this FDA clearance, the Company intends to advance several key initiatives as part of its growth strategy:

- **LIMITED LAUNCH**: Initiate a market introduction in early 2026, focusing on select concierge and preventive cardiology groups that have proactively signaled strong interest in adopting HeartBeam's technology. This limited market release will enable the Company to validate real world performance and establish reference sites for broader commercialization.
- **HEART ATTACK DETECTION**: Pursue a heart attack detection indication, supported by compelling proof-of-concept data and representing a major expansion opportunity to tens of millions of patients in the U.S.
- **EXTENDED WEAR PATCH**: Advance the on-demand 12-lead ECG extended wear monitor project. The Company has developed a working prototype of its novel 12-lead patch, which has the potential to be a best-in-class offering in an existing multi-billion-dollar market with reimbursement.
- **LONGITUDINAL DATA**: Unlock the power of the unique data-rich repository

generated from our 3D ECG platform. As adoption grows, the ability for patients to record synthesized 12-lead ECGs over time will create the opportunity to build AI-based screening and prediction algorithms that go beyond what is possible with single-timepoint ECGs or traditional wearables.

Robert Eno, Chief Executive Officer, HeartBeam commented, “The Company wishes to thank the FDA for its expeditious and constructive engagement throughout the review and appeal process, as well as its thorough evaluation of HeartBeam’s clinical data.

“This FDA clearance is a defining moment for HeartBeam, and the true beginning of our mission to revolutionize cardiac care. We look forward to initiating our U.S. market introduction while advancing our efforts on heart attack detection, an on-demand 12-lead extended wear patch, and AI-based screening and prediction algorithms trained on our unique longitudinal data.”

Robert A. Harrington, M.D., a world-renowned cardiologist and HeartBeam scientific advisory board member added, “One of the biggest challenges in cardiology is that cardiac symptoms most often don’t happen in the doctor’s office—they happen at home, at night, at work. The ability for patients to collect clinically meaningful ECG data at that exact moment, not hours later, can allow physicians to gain a much clearer understanding of a patient’s condition and take more timely action. HeartBeam is designed to be easy to carry and easy for patients to use, representing an important step forward in cardiac care.”

The Company plans to initiate a limited U.S. commercial launch in Q1 2026 with select concierge and preventive cardiology practices that have already signaled strong adoption interest. Additional details on broader geographic rollout, wearable integration, AI-enabled automated insights, and the Company’s heart attack detection program will be announced in the near future.

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 device capable of collecting ECG signals in 3D, from three non-coplanar directions, and synthesizing the signals into a 12-lead ECG. 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. HeartBeam’s 3D ECG technology received FDA clearance for arrhythmia assessment in December 2024 and the 12-Lead ECG synthesis software in December 2025[1]. The Company holds over 20 issued patents related to technology enablement. For additional information, visit HeartBeam.com.

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.

[1]Cleared Indications for Use

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.

The HeartBeam 12-Lead ECG Synthesis Software synthesizes a 12-Lead ECG from the HeartBeam System 3-Leads (in three-directions) recording device, producing a visual 12-Lead ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-Lead ECG. The synthesized 12-Lead ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The synthesized 12-Lead ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-Lead ECG. The 12-Lead ECG Synthesis Software is intended for adult use only.

For full safety information, see the full Instructions for Use or Clinician Portal Manual.

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