

HeartBeam Receives FDA Breakthrough Device Designation for Heart Attack Assessment

- *Designation recognizes the potential of HeartBeam's 3D ECG technology to help physicians assess suspected heart attacks outside the hospital*
- *Breakthrough status provides prioritized FDA interaction as HeartBeam advances toward a pivotal study*
- *Designation positions HeartBeam to pursue an expedited Medicare coverage pathway*
- *Updates on ALIGN-ACS data at TCT and the HEADSTART-ACS study expected in coming weeks*

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 U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the HeartBeam System as a tool for assessing potential heart attacks at home.

The designation recognizes the potential of HeartBeam's 3D ECG technology, which captures the heart's electrical signals from three non-coplanar dimensions, to enable physicians to evaluate signs of a possible heart attack (myocardial infarction, or MI) when symptoms start, wherever the patient may be. The FDA granted the designation within 30 days of HeartBeam's request, well ahead of the agency's 60-day statutory review period.

"One of the biggest gaps in heart attack care today occurs before the patient ever arrives at the hospital. While hospital systems have significantly improved time to treatment inside medical facilities, patients often still delay seeking care because symptoms can be subtle or easily dismissed," said Tony Das, M.D., a world-renowned cardiologist and HeartBeam scientific advisory board member. "HeartBeam's technology has the potential to address this gap by providing timely access to clinical-grade ECG data outside the hospital, which could enable earlier MI intervention."

More than 20 million U.S. adults are at elevated risk of a heart attack, yet the standard 12-lead ECG used to evaluate suspected MI is largely confined to hospitals and clinics. HeartBeam is developing its heart attack assessment capability on the same 3D ECG platform behind its FDA-cleared arrhythmia product and does not currently anticipate the need for new hardware development. The Company estimates the MI market opportunity at approximately \$15 billion within a broader cardiac platform opportunity of more than \$40 billion.

The FDA Breakthrough Devices Program is intended to provide patients and clinicians with more timely access to technologies that may offer more effective diagnosis or treatment of life-threatening or irreversibly debilitating conditions. The designation provides HeartBeam

with prioritized FDA review and interaction throughout development, including collaboration on the clinical and regulatory path toward potential clearance.

Breakthrough Device Designation is also a prerequisite for certain expedited Medicare coverage pathways. CMS and FDA have proposed the Regulatory Alignment for Predictable and Immediate Device (RAPID) pathway, under which CMS would issue a proposed national coverage determination on the same day an eligible Breakthrough Device receives FDA clearance. HeartBeam has also requested enrollment in FDA's Total Product Life Cycle Advisory Program (TAP).

"Receiving Breakthrough Device Designation is an important milestone for our heart attack detection program," said Branislav Vajdic, PhD, Founder and President of HeartBeam. "With heart attack detection now clearly established as HeartBeam's top strategic priority, the progress across our regulatory, clinical and development programs points to increasing momentum and an accelerating path forward. This designation deepens our engagement with the FDA as we work toward alignment on our pivotal study and positions us to pursue an expedited path to Medicare coverage. Both are critical steps toward our goal of giving physicians objective ECG information when heart attack symptoms begin, potentially helping patients seek appropriate care sooner."

HeartBeam's Breakthrough Device Designation was supported by proof-of-concept data presented at the 2025 American Heart Association Scientific Sessions and findings from the 134-patient ALIGN-ACS pilot study. The Company expects to seek FDA alignment on the design of a multicenter pivotal study in the coming months and anticipates beginning patient enrollment shortly thereafter. If successful, the study is intended to support a future submission to expand the HeartBeam System's indications to include heart attack assessment.

HeartBeam also expects to provide updates in the coming weeks on the ALIGN-ACS data presentation at the [TCT conference](#) and the HEADSTART-ACS study.

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 believes it has developed the first 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 received FDA clearance for arrhythmia assessment in December 2025¹. The Company holds more than 25 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.

¹Cleared Indications for Use

The HeartBeam System with 12-Lead ECG synthesis software for arrhythmia assessment received FDA clearance in December 2025. Refer to the Company's Cleared Indications for Use at <https://www.heartbeam.com/indications> for details on the intended use of its technology.

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