

HeartBeam's Heart Attack Assessment Technology Accepted into FDA's Total Product Life Cycle Advisory Program (TAP)

- *Acceptance into FDA's TAP Pilot follows Breakthrough Device Designation granted earlier this month for HeartBeam's heart attack assessment technology*
- *TAP Pilot provides dedicated FDA advisors and early engagement with payers, including CMS, as well as patient and provider organizations, to help accelerate future reimbursement and patient access*
- *Two FDA program milestones in less than one month underscore accelerating momentum behind HeartBeam's myocardial infarction (MI) program*

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 accepted the HeartBeam System into its Total Product Life Cycle Advisory Program (TAP) Pilot, a voluntary FDA program to accelerate patient access to Breakthrough medical devices. The acceptance, which was awarded ahead of schedule, applies to HeartBeam's 3D ECG technology, which received [FDA Breakthrough Device Designation](#) earlier this month, as a tool for assessing potential heart attacks outside of a medical setting.

[TAP Pilot](#) assigns dedicated FDA advisors who provide proactive regulatory support and coordinate expedited feedback. TAP also connects innovators with patient advocacy groups, healthcare provider organizations, and health insurance payers to address patient engagement, reimbursement, clinical adoption, and commercialization challenges early in development.

Breakthrough Device Designation and TAP together give innovators a more predictable route from FDA clearance to patient access and clinical adoption. Engaging payers early matters for a technology like HeartBeam's, where clinicians need confidence that ECG information obtained outside the hospital will be accessible and reimbursed for their patients.

"Acceptance into TAP, just weeks after Breakthrough Device Designation, gives us a structured partnership with FDA advisors and ongoing access to the stakeholders who will help determine how quickly patients can benefit from our 3D ECG technology for heart attack assessment, our top strategic priority," said Branislav Vajdic, PhD, Founder and President of HeartBeam. "We've already held our first meeting with our TAP advisors, and we are very excited about the level of engagement the FDA is providing the Company. We believe this positions us to move faster toward giving physicians objective, clinical-grade ECG information when heart attack symptoms begin, wherever the patient is."

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.

For HeartBeam, TAP builds on the Breakthrough Device Designation by adding ongoing engagement across the full product lifecycle, from clinical study design and regulatory submission through reimbursement and adoption. TAP's connection to payers is intended to allow HeartBeam to begin coverage and evidence discussions early, in parallel with development, rather than after clearance, which may include interactions with the Centers for Medicare & Medicaid Services (CMS). Breakthrough designation and TAP participation are also relevant to the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway announced by CMS and the FDA in April 2026, which is intended to accelerate Medicare beneficiary access to eligible Breakthrough devices. HeartBeam is currently evaluating its eligibility for RAPID with its TAP advisor.

The Company expects to seek FDA alignment on the design of its multicenter pivotal study in the coming months and anticipates beginning patient enrollment in Q1 2027. If successful, the study is intended to support a future submission to expand the HeartBeam System's indications to include heart attack assessment.

Enrollment in TAP does not change any statutory or regulatory requirements applicable to HeartBeam's device, and does not guarantee that a future submission will receive FDA authorization or that coverage will be granted. The HeartBeam System is not currently cleared for heart attack detection and its use in clinical studies is investigational.

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.

MKT-170 v0

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20261026049593/en/>

Media Contact:

media@heartbeam.com

Investor Relations Contact:

Chris Tyson

Executive Vice President

MZ North America

Direct: 949-491-8235

BEAT@mzgroup.us

www.mzgroup.us

Source: HeartBeam, Inc.