

EchoNext Clears FDA for Six Structural Heart Conditions Off a Standard ECG, Lands on OpenEvidence, and Logs the First AI-Triggered Heart Transplant: Reading the Cardiac Screening Land Grab

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Pathway Labs cleared the FDA for six structural heart conditions off one ECG. The \$8.5M seed round is the least interesting part of this announcement...

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Heart Transplant: Reading the Cardiac Screening Land Grab

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Abstract

Pathway Labs launched EchoNext, an AI tool that reads a standard 12-lead ECG and flags six structural heart conditions, billed as the first multi-condition cardiology AI cleared by FDA. Targets: low EF (left and right heart failure), valve disease, severe hypertrophy consistent with infiltrative cardiomyopathy, and pulmonary hypertension. Trained on 700k+ ECG-echo pairs at NewYork-Presbyterian, validated across multiple hospital systems and ~500k patients in the US and Canada, reportedly beating cardiologists, including cardiologists using AI. Founder/CEO Pierre Elias,



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MD (NYP AI medical director, Columbia). Seed: \$8.5M led by AlleyCorp and Breyer Capital, with NYP also in. Distribution kicker: licensed onto OpenEvidence, which claims roughly 40%+ of US physicians and about 757,000 verified clinicians. A June 22, 2026 Nature Medicine case ties an EchoNext flag to what the company calls the first AI-driven heart transplant. Competitive frame: single-indication ECG-AI from Anumana (Mayo/nference) and Tempus, plus the Category III CPT and OPPS reimbursement plumbing already laid down. Thesis: the clearance is the table stakes, the OpenEvidence pipe is the moat, and the unsolved problem is downstream echo capacity and positive predictive value at population scale.

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The thing everyone is misreading about the raise

The number in every headline is 8.5 million dollars, and that number is the least interesting thing in the announcement. A seed that size for a Columbia and NewYork-Presbyterian spinout with an FDA clearance already in hand is almost a rounding error, the kind of round that exists mostly to put a price on the cap table and let two name-brand funds plant a flag. AlleyCorp and Breyer Capital led it, NYP put money in, and that is a perfectly fine seed. Anyone reading the dollar figure as the story is reading the wrong line of the press release.

The actual story sits in three other facts stacked on top of each other. There is a regulatory fact, which is that the clearance covers six conditions at once rather than one. There is a distribution fact, which is that the product is going out through OpenEvidence rather than through a five-year health system sales grind. And there is a clinical proof-point fact, which is a published case where an algorithm reading a routine tracing set off a chain that ended in a transplant. Each one of those is more valuable than the seed. Together they describe a company that has solved the two things that usually kill cardiac AI, which are getting cleared for something worth paying for and getting the thing in front of a doctor who will act on it.

So the rest of this is about those three facts, what they cost to replicate, and who in the existing ECG-AI field just had a worse week than they are admitting.

What the model is actually doing to a tracing

EchoNext takes a standard twelve-lead electrocardiogram, the same squiggle that gets run roughly 100 million times a year in the US, and predicts whether the heart underneath that tracing has structural disease that an echocardiogram would catch and a human reader would not. The clearance covers six indications, which in plain terms are reduced pumping function on the left and the right side, valve disease, severe wall thickening of the kind that travels with infiltrative disease like amyloid, and elevated pulmonary pressures. These are conditions that frequently look like a vaguely abnormal ECG and nothing more until the patient is already symptomatic and already in trouble.

The training set is the part worth lingering on, because it is the moat that money cannot quickly buy. The model learned on more than 700,000 paired ECG and echocardiogram studies from inside the NewYork-Presbyterian system, which means every input tracing had a matched ground-truth imaging answer attached to it. That pairing is the expensive thing. Plenty of groups have millions of ECGs lying around. Far fewer have millions of ECGs each cleanly linked to the echo that tells you what the heart was actually doing. Validation then ran across four hospital systems and hundreds of thousands of patients, and the company reports the model outperformed cardiologists, including cardiologists who themselves had AI assistance. In a head-to-head comparison with 13 cardiologists evaluating 3,200 ECGs, EchoNext correctly identified 77% of structural heart problems, while cardiologists making diagnoses with the same ECG data achieved an accuracy of 64%.

The relevant peer-reviewed work landed in *Nature*, and a separate *Nature Medicine* case in June walked through a single patient whose EchoNext flag, on an ECG that looked abnormal but unrevealing, eventually surfaced severe dysfunction, a leaking mitral valve, an inherited arrhythmia syndrome, and a transplant. One patient is an anecdote, not an outcomes trial, but it is a very well-placed anecdote.

The framing the founder keeps using is the cancer-screening analogy, and it is doing real rhetorical work. Mammography and colonoscopy gave oncology an organized way to catch disease before symptoms. Cardiology, despite owning the leading cause of death for a hundred years running, never built that lane. The pitch is that the ECG, already ordered everywhere, already cheap, already sitting in the chart, becomes the screening test that never existed, with the AI as the thing that reads the part of it no human can see.

Why an abnormal ECG is a firehose, not a flag

Here is the problem the analogy quietly skips, and to the company's credit the founder says it out loud. Abnormal ECGs are not rare. A huge share of tracings get read as abnormal in some nonspecific way, and the clinical value of that label is close to zero because it is so common. The founder's own line is that if every abnormal ECG triggered an echo, the system would go broke. That is not a throwaway quote. It is the entire economic thesis of the product compressed into one sentence.

What EchoNext is selling, then, is not detection in the abstract. It is triage. It is a way to take the firehose of abnormal tracings and turn it into a much smaller, much higher-yield list of patients who should actually get the downstream echo. The value is in the narrowing. A screening tool that simply flagged more things would be a liability generator, because every flag is a referral, an imaging slot, a specialist visit, and a bill. A screening tool that flags the right things shifts echo capacity toward the patients who needed it and away from the worried well, and that is a number a CFO can model.

This is also where the population math gets uncomfortable in a way the launch materials gloss. Run an imperfect classifier across 100 million tracings and even an excellent positive predictive value still produces an enormous absolute pile of false positives, simply because the denominator is gigantic and structural disease, while deadly, is not present in most people walking in for a routine ECG. Every one of those false positives is a real human getting a real echo they did not need, plus the anxiety tax of being told a computer is worried about their heart. The product lives or dies on whether the flag rate is calibrated tightly enough that the downstream system can absorb the true positives without drowning in the false ones. That is a deployment problem, not a model-accuracy problem, and the two get conflated constantly.

One condition at a time was the old game

The word that does the competitive heavy lifting in this announcement is multi-condition. Until now the ECG-AI field has mostly been a one-indication-at-a-time business, and that structure shaped who built what and how they got paid.

Anumana, the inference and Mayo Clinic venture, basically wrote the early playbook. It pulled FDA breakthrough designations and then clearances for single targets, starting with low ejection fraction, then extending toward cardiac amyloidosis, pulmonary hypertension, and hyperkalemia, each as its own model with its own evidence package. Tempus, now public, followed the same one-target logic, clearing

an atrial fibrillation risk model and then a low EF model whose own filing leaned on Anumana's clearance as the predicate. That predicate detail is telling. The first mover in a single indication sets the bar that the next entrant has to match, and the regulatory contest becomes a series of narrow head-to-head fights over the same condition.

EchoNext sidesteps that by clearing a bundle. Instead of competing for the low EF crown against well-funded incumbents, it shows up with six conditions under one product and one workflow, and reframes the category from a collection of single-disease detectors into a general structural-heart screen. That is a positioning move as much as a technical one. It lets the company tell a hospital that one integration covers the waterfront rather than asking them to stitch together four vendors for four diseases. It also raises the replication cost for anyone trying to copy the approach, since matching a six-condition clearance means assembling six evidence packages and the paired imaging data behind each. The incumbents are not beaten, they have deeper pockets and longer head starts on their specific targets, but the ground just shifted under the question of what a buyer is even buying.

Whether multi-condition is genuinely better medicine or mostly better packaging is an open question worth holding. A specialist might reasonably prefer a model purpose-built and separately validated for amyloid over a generalist that touches amyloid among five other things. The bundle wins on workflow and procurement. The single-indication tools may still win on depth for the conditions where depth matters most. Both can be true.

Who actually pays for an algorithm that reads a squiggle

Reimbursement is where cardiac AI dreams have historically gone to get a reality check, and the plumbing here is specific enough to be worth knowing. The American Medical Association created Category III CPT codes for assistive algorithmic ECG analysis of cardiac dysfunction, the well-known pair being the codes Anumana drove through. CMS then folded those into the hospital outpatient payment system, assigning them to an ambulatory payment classification with a national outpatient rate sitting around 128 dollars and change, effective at the start of 2025, under the policy that lets certain software-as-a-service diagnostics get paid in the outpatient setting.

That sounds like a solved problem and it mostly is not. Category III codes are by design temporary and emerging, carrier-priced in many settings, which means the actual dollars vary by region and by Medicare contractor, and commercial coverage

trails behind in the usual ragged way. In the inpatient setting the diagnostic generally vanishes into the bundled payment for the admission unless it qualifies for a new-technology add-on, which is its own application marathon. The lesson from the broader AI-reimbursement saga, the one playing out across the cardiac imaging vendors and the coronary CT analysis companies, is that a code existing and a code paying real money at scale are different milestones separated by years and a lot of payer-relations labor.

This is exactly why the OpenEvidence move matters so much, and it is the connective tissue between the boring reimbursement section and the interesting distribution section. If getting paid per-use through the fee schedule is slow and uneven, then a distribution model that does not depend on per-click reimbursement to reach the doctor changes the calculus. A tool that has to be sold to a hospital, integrated into the ECG cart workflow, and then billed under a wobbly Category III code has a long road. A tool that simply appears inside software the physician already opens dozens of times a day has skipped most of that road. The clearance lets it be used. The distribution decides whether it actually is.

The real asset is the distribution, not the clearance

OpenEvidence is the most interesting company in this entire story, and it is not even the one that raised the money. It is the doctor-facing clinical search tool that, depending on the week's figures, claims something north of 40 percent of US physicians and roughly 757,000 verified clinicians, with tens of millions of clinical consultations a month, and a multibillion-dollar valuation off a late-stage round that sharply increased its price. It runs on advertising, mostly pharma, served at the moment a physician is asking a clinical question, which is why its ad rates run at CPMs that make ordinary digital advertising look like a garage sale. It got there bottom-up, doctor by doctor, bypassing the eighteen-month hospital procurement crawl, with most new users hearing about it from another physician rather than from a sales rep.

Putting EchoNext on that platform is the whole game. It means a structural-heart screen reaches the point of care through a channel that already solved the hardest problem in health tech, which is getting a busy clinician to actually open the tool. STAT reported that doctors using OpenEvidence will soon be able to upload an image of an electrocardiogram to get an algorithmic prediction of whether a patient has structural heart disease, which makes the distribution story concrete rather than

theoretical. If that workflow sticks, EchoNext does not need to win the hospital IT battle first in order to matter.

That also explains why the clearance and the platform deal belong in the same sentence. FDA clearance is permission. Distribution is usage. In health tech, permission without usage is a museum piece.

Two bets converging, and what Breyer is really signaling

Breyer Capital's presence on the seed is not just a financing fact; it is a signal about where smart capital thinks the value is moving. The first bet is obvious: that cardiac AI will not remain a one-off anomaly detector, but will become a broader screen for structural disease embedded in routine care. The second bet is subtler: that the place to own the clinical workflow may matter more than the model itself.

Those bets converge on a simple idea. If the algorithm is good enough and the platform is sticky enough, the company that owns the distribution layer can decide which clinical modules matter, how often they are used, and who gets pulled into the downstream diagnostic funnel. That is a more powerful position than selling a standalone model into a health system that may never fully deploy it. It is also a harder position to build, which is why the OpenEvidence relationship is worth more strategic attention than the seed round itself.

Where this gets hard, and what to watch next

The hard part is no longer whether an algorithm can read an ECG better than a human at a specific task. The hard part is whether the system around the algorithm can absorb the consequences. If EchoNext works as advertised, it will generate work: echocardiograms, follow-up visits, anxiety, incidental findings, and a lot of questions about when not to act. The next question is whether the company can show that the flags change outcomes rather than just redistributing diagnostics.

The other thing to watch is whether the multi-condition frame holds up in practice. A product that flags six conditions from one tracing is more elegant to pitch than a patchwork of narrow tools, but buyers will eventually ask which conditions matter most, which ones are validated tightly enough for high-stakes use, and whether the tool meaningfully improves the yield of the downstream echo slot. That is where the story either becomes screening infrastructure or gets reduced to another smart algorithm with a nice launch.

And the last thing to watch is whether the OpenEvidence channel becomes a genuine moat or just a convenient starting point. If the tool converts physician attention into action, that is a durable advantage. If it becomes another feature buried in a crowded clinical software environment, then the clearance will still matter, but less than the press release suggests

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