

CLEERLY HEALTH AI PLAQUE ANALYSIS

ESSAY DRAFTS

1. Turnover and/or Funding

Through proven results and widespread adoption, Cleerly has paved the way to transform cardiac care. The company's financial performance, strategic partnerships, and regulatory achievements demonstrate consistent growth and market validation.

The company has raised over \$383 million across four funding rounds, with each round showing increasing investor confidence. The progression started with an \$11 million Series A, followed by a \$43 million Series B in 2021. A significant milestone came with a \$223 million Series C-1 round in 2022, one of the largest investments in cardiac AI diagnostics at the time. This growth continued with a \$106 million Series C-2 round in December 2024, led by Insight Partners, bringing total Series C funding to \$329 million.

This funding growth reflects real market demand rather than speculation. Cleerly has nearly doubled its revenue annually over the past three years, demonstrating that healthcare providers value the technology.

The company has built strategic partnerships that expand its market reach. Key collaborations with Heartbeat Health (2022), Viz.ai (2024), Bunkerhill (March 2025), and Cardiac Care Alliance (May 2025) have opened access to cardiology offices, imaging centers, and hospital systems. These partnerships show that the industry recognizes how Cleerly's platform addresses real clinical needs.

Cleerly's regulatory achievements have enabled commercial adoption. FDA clearance in November 2019 validated the technology's safety and efficacy. A major commercial milestone came in 2024 when Medicare coverage was approved by five of seven Medicare Administrative Contractors, providing access for approximately 67 million Medicare beneficiaries. The recent approval of a CPT I code for Cleerly LABS Plaque Analysis, effective January 2026, will further improve reimbursement access.

Current market presence demonstrates the technology's clinical value. As of July 2025, Cleerly delivers 30,000 analyses annually to over 2,000 customers across primary care, hospitals, cardiology practices, and imaging centers. This adoption shows that the technology works effectively in real-world clinical settings.

Cleerly's progress combines strong financial backing, strategic partnerships, regulatory clearances, and growing market demand. These factors have created a solid foundation for continued growth in the cardiovascular diagnostics market.

2. Indications

Cleerly LABS is an AI-powered diagnostic tool that analyzes CCTA images to detect and characterize coronary artery plaque, providing physicians with comprehensive insights for cardiovascular disease evaluation and management.

The FDA-cleared indications for use are as follows: Cleerly LABS is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post-processes CT images obtained using any Computed Tomography (CT) scanner.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

The clinical workflow begins when a physician identifies a Cleerly candidate, after which the patient visits a Cleerly-enabled CCTA imaging facility. The patient's scan is securely uploaded to Cleerly for AI analysis, and a comprehensive report is delivered to the physician or clinic. The machine-learning AI generates a 3D model of the patient's coronary arteries, identifies lumen and vessel walls, locates and measures stenoses, and quantifies and categorizes plaque composition and burden.

Cleerly LABS serves patients with suspected CAD requiring diagnostic evaluation, patients presenting with chest pain, and those requiring pre-operative cardiac risk assessment. The technology is particularly valuable for patients with intermediate pre-test probability of CAD where traditional testing may be inconclusive, and for individuals seeking comprehensive plaque characterization to guide preventive therapy decisions.

Key clinical applications include outpatient assessment of patients with atypical chest pain symptoms, preventive cardiology evaluation for risk stratification and early intervention planning, pre-procedural planning for patients considering coronary interventions, and longitudinal monitoring of plaque progression in patients with established coronary disease. The technology also supports clinical decision-making for patients with equivocal stress test results and those requiring detailed anatomical assessment before cardiac surgery.

Cleerly LABS addresses critical diagnostic needs across diverse cardiovascular patient populations, providing AI-enhanced analysis that enables precise, individualized coronary artery disease evaluation and supports clinical decision-making from emergency settings to preventive care.

3. Therapeutic Areas

Cleerly LABS impacts multiple medical specialties through its comprehensive AI-driven coronary artery analysis, transforming cardiovascular care delivery across the healthcare continuum.

In cardiology, interventional cardiology, and cardiac surgery, Cleerly LABS provides detailed anatomical data for cardiovascular interventions and pre-procedural planning. The technology identifies candidates for coronary revascularization and enables precise planning based on plaque characteristics and vessel anatomy. For cardiac surgeons, the platform delivers critical insights into coronary anatomy that inform surgical approach and risk assessment, while interventional cardiologists benefit from comprehensive plaque characterization, accurate stenosis measurements, and the likelihood of ischemia, that guides device selection and procedural strategy.

Within preventive medicine, the technology identifies high-risk plaque characteristics that drive major adverse cardiovascular events, enabling earlier diagnosis and precision treatment before symptom development. This capability transforms preventive cardiology by moving beyond traditional risk factor assessment to direct visualization of subclinical atherosclerosis, allowing for personalized risk stratification and targeted interventions.

For diagnostic radiology and medical imaging specialists, Cleerly LABS streamlines the CCTA evaluation process with automated, comprehensive reporting while delivering diagnostic accuracy comparable to invasive gold standards¹⁻³. The technology reduces interpretation time and improves diagnostic consistency across imaging centers,

providing quantitative measurements in accessible formats that support clinical decision-making. Radiologists benefit from standardized reporting templates and automated measurements that enhance workflow efficiency while maintaining diagnostic precision.

In acute care scenarios, Cleerly LABS enables noninvasive assessment of patients presenting with acute chest pain, identifying those requiring intervention. The technology supports clinical decision-making by providing comprehensive coronary evaluation that can rule out significant coronary artery disease or identify high-risk features requiring management. This capability enhances efficiency while improving patient outcomes through more precise risk stratification.

For internal medicine and primary care physicians, Cleerly LABS supports comprehensive disease management through detailed baseline evaluation and tracking of therapeutic interventions through additional imaging assessment. Primary care physicians gain access to sophisticated cardiovascular risk assessment tools that inform long-term management strategies, while internists can monitor treatment effectiveness and disease progression with quantitative precision. The technology bridges the gap between primary care and specialized cardiovascular services by providing actionable insights for non-specialists.

Cleerly LABS transforms cardiovascular medicine by providing AI-enhanced diagnostic capabilities that span multiple medical specialties, enabling more precise, personalized, and effective patient care across the healthcare ecosystem.

4. Background Information and Need for Drug/Device

Despite being the leading cause of death in the US and globally, cardiovascular disease remains poorly diagnosed and inadequately prevented, creating an urgent need for advanced diagnostic technologies that can accurately identify at-risk patients before cardiac events occur.

Heart disease accounts for over 900,000 fatalities annually¹, which is more than all cancers combined. Coronary artery disease (CAD), the most common type of heart disease, occurs when plaque builds up in the heart's arteries. Despite advances in medical care, 90% of heart attacks are estimated to be preventable, yet many individuals remain unaware of their cardiovascular risk.²

Additionally, there is a disconnect between disease severity and clinical events which is a critical diagnostic challenge in current cardiovascular care. A fundamental

misconception that persists is that heart attacks only occur when arterial blockages are severe or blood flow is significantly reduced. However, more than 75% of plaques leading to heart attacks cause only mild stenosis.³

A critical limitation in cardiology today is the inadequacy of traditional diagnostic methods in accurately assessing cardiovascular risk. Research indicates that the presence of high-risk soft plaque represents the most accurate predictor of fatal heart attacks,⁴ yet traditional clinical assessment methods fail to detect this critical risk factor.

Currently, many healthcare providers depend on coronary artery calcium scoring, stress testing, and conventional risk factor assessment. Unfortunately, these methods do not accurately measure the heart's current disease state, with 70% of heart attack victims classified as low-risk by traditional assessment methods.⁵ Calcium scoring, which many healthcare providers depend on, provides incomplete disease characterization, as a score of zero indicates no calcified plaque but cannot exclude the presence of high-risk non-calcified plaque that may precipitate cardiac events, which occurs in upwards of 30% of heart attacks.⁶

The asymptomatic nature of cardiovascular disease compounds diagnostic challenges, with over 50% of individuals who die or suffer from a heart attack experiencing no symptoms before the event.⁷ This asymptomatic presentation creates a diagnostic blind spot that current screening methods cannot adequately address.

Unsurprisingly, these diagnostic limitations result in significant clinical care gaps and inappropriate clinical interventions. Fifty percent of stents placed in patients with stable chest pain are possibly or definitely inappropriate, meaning half of patients with stents derive no clinical benefit.^{8,9} Similarly, 66% of cardiac catheterization referrals are unnecessary, with two in three patients receiving invasive procedures they do not require.¹⁰ Additionally, 90% of cardiac stress tests yield normal results, indicating that nine in ten patients undergo unnecessary specialist referrals.¹¹ These systemic diagnostic failures, from the inability to detect high-risk plaque to the overreliance on symptom-based assessment, demonstrate the critical need for precision diagnostic tools that can accurately characterize coronary disease, reduce inappropriate interventions, and enable early identification of patients at genuine cardiovascular risk. Advances in imaging technologies and the development of AI-driven technologies like Cleerly LABS, represent essential innovations for addressing these fundamental gaps in cardiovascular care.

5. Development & Clinical Evidence

Cleerly LABS is transforming cardiovascular diagnostics through systematic clinical validation that demonstrates not only superior accuracy compared to current methods, but fundamental improvements in how physicians diagnose and treat coronary artery disease.

Cleerly's prospective multicenter CERTAIN trial evaluated 750 patients across five U.S. sites to compare Cleerly's technology against conventional coronary CT angiography interpretation by expert level III imaging physicians. This rigorous study revealed that Cleerly's comprehensive evaluation fundamentally changed how physicians approach patient care, leading to significant changes in clinical decision-making and patient management in more than 57% of cases while increasing diagnostic confidence up to five-fold. The technology's impact extended across the entire care continuum, resulting in a 39% change in stenosis assessment, a 37% reduction in unnecessary further testing, and a 28% increase in preventive medication use.¹

Building on this clinical utility, validation studies demonstrate that Cleerly achieves superior diagnostic accuracy compared to established cardiovascular testing methods. When disagreements occurred between quantitative invasive angiography and Cleerly's AI-guided quantitative coronary CT angiography (AI-QCT) analysis, Cleerly showed higher agreement with the gold standard invasive fractional flow reserve (FFR), correctly identifying more than two-thirds of vessels with true ischemia.² This superior performance extends beyond stenosis assessment, with studies showing that Cleerly outperforms myocardial perfusion imaging for detecting obstructive coronary artery disease and demonstrates high agreement with near-infrared spectroscopy for identifying dangerous lipid-rich plaques.^{3,4}

The clinical significance of this improved accuracy becomes clear when examining how Cleerly addresses a fundamental problem in current cardiovascular care: diagnostic overestimation. Clinical readers routinely overestimate stenosis severity, leading to unnecessary downstream interventions that expose patients to risk without benefit. Cleerly identifies 53% fewer false positive significant stenoses compared to clinical readers, directly addressing this overtreatment problem that contributes to healthcare inefficiency and patient harm.⁵

Perhaps most importantly for preventive cardiovascular medicine, Cleerly enables early disease detection that was previously impossible with conventional methods. Serial imaging studies demonstrate that 87% of coronary plaques detected on follow-up examinations were present as small, early lesions on baseline scans, with 72% showing disease progression over time.⁶ This capability transforms cardiovascular care from reactive treatment of symptomatic disease to proactive prevention through early intervention before significant stenosis develops.

This comprehensive clinical evidence demonstrates that Cleerly LABS represents a fundamental advancement in cardiovascular diagnostics, with rigorous validation showing that the technology not only achieves superior diagnostic accuracy but transforms clinical practice by improving physician decision-making, reducing unnecessary interventions, and enabling the shift from reactive treatment to preventive cardiovascular medicine.

6. History of Development

Cleerly LABS emerged from a recognized need to transform cardiovascular diagnostics from symptom-based assessment to direct visualization of coronary artery disease, bridging decades of clinical research with AI-driven innovation.¹⁻²

Cleerly's development was spearheaded by founder and CEO James K. Min, MD, whose distinguished academic career has included positions as Professor of Radiology and Medicine at Weill Cornell Medical College and Director of the Dalio Institute of Cardiovascular Imaging at NewYork-Presbyterian. His clinical and research focus on coronary artery disease produced more than 500 peer-reviewed manuscripts, establishing him as a leading authority in cardiovascular imaging science.

Dr. Min's research leadership on landmark multicenter clinical trials, including ACCURACY³, CONFIRM⁴, CONSERVE⁵, CREDENCE⁶, ICONIC⁷, and PARADIGM⁸, provided critical insights into existing diagnostic limitations. His experience directing core laboratories for the PACIFIC⁹ and ISCHEMIA¹⁰ trials revealed a fundamental gap: while atherosclerosis drives cardiovascular events, traditional assessment methods rely on indirect risk factors rather than direct disease visualization. This clinical insight led Dr. Min to found Cleerly to translate his 17 years of clinical trial research into practical coronary heart disease solutions.

Building on this research foundation, Cleerly was founded in 2017 with the mission to eliminate heart attacks through AI-driven diagnosis. The early development was focused on addressing the disconnect between traditional cardiovascular care's symptom-based approach and the need for direct atherosclerosis assessment. The technical development process began with assembling a database of over 10 million images from more than 40,000 patients accumulated across Dr. Min's clinical trial experience.

This extensive dataset enabled the Cleerly team to develop proprietary machine learning algorithms using validated convolutional neural networks specifically designed

for comprehensive CCTA analysis. The development process included creating automated coronary segmentation capabilities, sophisticated lumen and vessel wall determination systems, and advanced plaque quantification algorithms. Simultaneously, the team established a cloud-based software platform architecture to enable rapid, scalable analysis for clinical deployment.

The transition from development to regulatory validation marked a critical milestone when Cleerly LABS received FDA 510(k) clearance (K190868) in November 2019, demonstrating the technology's safety and efficacy for clinical use. This regulatory achievement was followed in 2020 by the CPT Editorial Panel's acceptance of 17 Category III codes (0623T-0639T), including Cleerly-specific codes 0623T-0626T, establishing essential billing and reimbursement pathways for clinical adoption.

Additional pivotal validation of the technology's clinical utility occurred in November 2024, when Medicare Administrative Contractors coverage for AI-QCT scans took full effect for Medicare recipients with stable and acute symptoms suspicious of coronary artery disease, impacting approximately 67 million beneficiaries. Looking forward, a new Category I CPT code for Cleerly's AI-QCT advanced plaque analysis will take effect on January 1, 2026, further solidifying integration into standard clinical practice.

Cleerly's evolution from academic research to becoming a clinical tool demonstrates how scientific, combined with technological innovation, can transform patient care through precision medicine that directly addresses cardiovascular disease.

[Accompanying Product Images Here](#)

7. Innovation and Human Condition Impact

Heart disease remains the leading cause of death in the United States and worldwide, yet current diagnostic approaches do not prevent the majority of cardiac events. To address this critical gap in human health, Cleerly LABS represents a fundamental innovation that transforms cardiovascular care from symptom-based treatment to direct disease prevention.

Traditional cardiovascular care relies on indirect markers including cholesterol levels and symptoms, like chest pain, rather than assessing the underlying atherosclerotic disease. This approach misses around 70% of heart attack victims, who are classified as "low risk" by conventional methods.¹ Additionally, 75% of heart attack-causing lesions cause only mild narrowing, making them undetectable by standard testing.² These diagnostic limitations result in preventable deaths.

Cleerly's innovation provides an automated platform for direct, quantitative atherosclerosis assessment. The technology enables physicians to visualize and characterize coronary plaque burden before symptoms develop, fundamentally changing how cardiovascular disease is detected and prevented. This direct assessment approach addresses the root cause of cardiac events rather than waiting for downstream consequences.

Furthermore, clinical evidence of Cleerly LABS demonstrates immediate impact on patient care. The CERTAIN study showed management changes in over 57% of patients and five-fold increases in physician diagnostic confidence.³ Prognostic studies establish superior risk prediction compared to current clinical standards,⁴ while the CONSERVE trial demonstrated 77% reductions in unnecessary invasive procedures while maintaining safety.⁵ These results highlight Cleerly technology's ability to improve patient outcomes while reducing healthcare burden.

The ongoing TRANSFORM randomized controlled trial aims to establish screening protocols for asymptomatic individuals. This population represents the majority of future heart attack victims; with 7,500 patients planned for enrollment, the results for this trial are expected in 2028. TRANSFORM's approach mirrors successful cancer screening programs that have dramatically reduced mortality through early detection.

Cleerly's vision is to eliminate preventable heart attacks by transforming cardiovascular care from reactive treatment to precision prevention. The technology enables early identification and targeted intervention for high-risk patients while avoiding overtreatment, ultimately reducing healthcare costs and advancing the mission of innovation to improve the human condition. Given heart disease's status as the leading global killer, this technology introduces a clinical paradigm grounded in predictive insight and prevention.

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