FDA Clears HeartLung's AI-CVD®, Enabling the Broadest Opportunistic Cardiovascular & Multisystem CT Screening Platform

FDA-cleared AI-CVD® extracts preventive insights from routine CT—identifying hidden cardiovascular, metabolic, and skeletal risk in ~40M scans/year
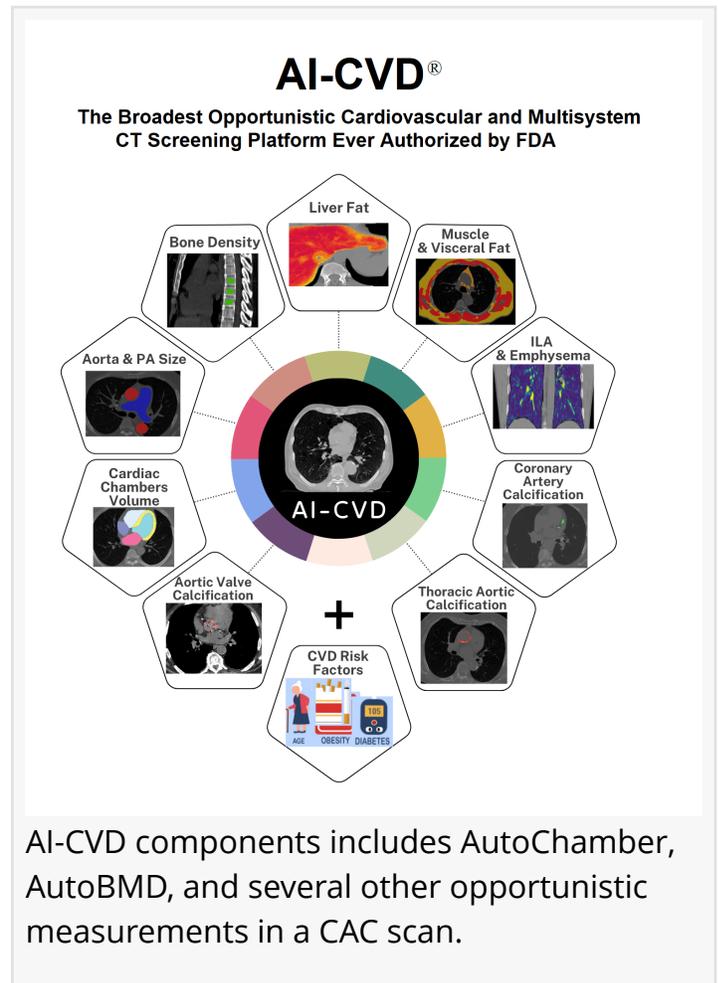
HOUSTON, TX, UNITED STATES, January 12, 2026 /EINPresswire.com/ -- HeartLung Corporation today announced U.S. Food and Drug Administration (FDA) clearance of AI-CVD ®, its flagship AI-powered quantitative imaging platform, under 510(k) K252029, marking a major inflection point in preventive medicine and opportunistic screening.

With this clearance, AI-CVD® becomes the most comprehensive FDA-cleared opportunistic screening platform available for CT imaging, enabling automated extraction of clinically relevant cardiovascular and systemic measurements from existing chest and abdominal CT scans—without additional imaging, radiation, contrast, or workflow disruption.

AI-CVD components includes AutoChamber, AutoBMD, and several other opportunistic measurements in a CAC scan.

FDA-cleared AI-CVD® can be applied to nearly 40 million CT scans performed annually in the United States, representing approximately half of all CT scans, and up to 80 million scans when including head and extremity imaging, transforming routine diagnostic imaging into a powerful, scalable engine for early detection and prevention.

A New FDA-Cleared Standard for Opportunistic Screening

AI-CVD® is an opportunistic, AI-powered quantitative imaging tool that provides automated CT-derived anatomical and density-based measurements for clinician review.

Using AI-CVD® quantitative imaging measurements and clinical evaluation, healthcare providers can investigate patients who are unaware of their risk of:

Coronary heart disease

Heart failure

Atrial fibrillation

Stroke

Osteoporosis

Liver steatosis

Diabetes

Other adverse health conditions that may warrant follow-up

Ten FDA-Cleared Opportunistic Measurement Domains in a Single Platform

AI-CVD® includes FDA-cleared modules for:

Coronary artery calcium (CAC) scoring

Aortic wall calcium

Aortic valve calcium

Mitral valve calcium

Cardiac chamber volumetry

Epicardial fat volumetry

Aorta and pulmonary artery sizing

Lung attenuation analysis

Liver attenuation analysis

Bone mineral density and muscle–fat composition

All volumetric measurements are adjusted for body surface area and reported in absolute values and population-based percentiles, referenced to the Multi-Ethnic Study of Atherosclerosis (MESA) and Framingham Heart Study (FHS).

"For decades, medicine has waited for patients to declare disease. AI-CVD® allows us to find disease while it is still silent—using scans that already exist," said Dr. Morteza Naghavi, Founder and President of HeartLung Corporation. "This FDA clearance represents a fundamental shift: CT is no longer just diagnostic imaging—it becomes a scalable, opportunistic prevention platform capable of identifying risk across the heart, lungs, bones, liver, and metabolism in a single pass."

By converting routine imaging into a multi-disease prevention platform, AI-CVD® addresses one of healthcare's most persistent failures—missed opportunities to detect silent disease before irreversible events occur.

Advisory Board Perspectives

AI-CVD® builds directly on the scientific foundations of modern cardiovascular imaging, as emphasized by members of HeartLung's Scientific Advisory Board.

"Coronary calcium revealed long ago that atherosclerosis begins well before symptoms," said Arthur Agatston, MD, Clinical Professor of Medicine, Florida International University, and developer of the Agatston Coronary Calcium Score. "AI-CVD® extends that insight by enabling systematic identification of patients who are unaware of their cardiovascular risk—using CT scans that already exist."

From the radiology perspective, the power of opportunistic screening lies in extracting more value from imaging already embedded in care pathways.

"Modern CT contains far more clinically meaningful information than we traditionally extract," said David Yankelevitz, MD, Professor of Radiology, Icahn School of Medicine at Mount Sinai, and Co-Principal Investigator of IELCAP. "AI-CVD® allows clinicians to leverage routine CT scans responsibly and efficiently, without adding imaging burden. That is exactly how opportunistic screening should be done and we are now entering the new domain of comprehensive screening"

AI-CVD® also reflects a growing recognition that cardiovascular disease is inseparable from

broader systemic risk.

"Cardiovascular disease rarely exists in isolation," said Zahi Fayad, PhD, Professor of Radiology and Medicine and Director of the BioMedical Engineering and Imaging Institute at Icahn School of Medicine at Mount Sinai. "By integrating quantitative measurements across the heart, vasculature, lungs, liver, bone, and body composition, AI-CVD® provides a scientifically grounded framework to identify individuals who may benefit from closer evaluation across multiple disease domains."

The clinical impact of uncovering silent disease was underscored by translational experts.

"Many of the most serious cardiovascular and metabolic conditions progress silently for years," said Robert Kloner, MD, PhD, Director of the Cardiovascular Research Institute at Huntington Medical Research Institutes and Professor of Medicine at the Keck School of Medicine of USC. "This AI allows identification of structural abnormalities that the human eye may otherwise miss, hence helping to bring hidden risk into clinical focus, enabling informed decisions about further evaluation and prevention."

Despite decades of progress, primary prevention today still relies largely on traditional risk factors and population-based scores, which frequently miss individuals with substantial subclinical disease. Opportunistic, CT-based quantitative imaging offers a long-overdue opportunity to modernize prevention by directly identifying structural and calcific disease burden rather than inferring risk indirectly.

""Primary prevention has long depended on risk factors and probability scores, yet we continue to see cardiovascular events in patients who were never identified as high risk. Quantitative CT findings—such as markedly elevated coronary calcium and enlargement of cardiac chambers, particularly the left atrium and ventricle—directly reveal underlying disease burden. AI-CVD® provides a scalable, FDA-cleared pathway to incorporate these objective phenotypes into preventive care, representing a necessary evolution of modern prevention."— Nathan D. Wong, PhD, MPH, FACC, FAHA, FNLA, MASPC Professor of Medicine; Director, Heart Disease Prevention Program; Co-Director, Center for Global Cardiometabolic Health and Nutrition, University of California, Irvine; Past President, American Society for Preventive Cardiology

Transforming CT from Diagnostic Imaging into Preventive Infrastructure

Unlike traditional screening programs that require dedicated exams, referrals, and reimbursement pathways, AI-CVD® operates as an opportunistic add-on to CT scans already being performed for other clinical indications, including:

Lung cancer screening CT

Coronary calcium scans

Diagnostic chest CT

Coronary CT angiography (CCTA)

CT pulmonary angiography (CTPA)

Abdominal and pelvic CT

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A Category-Defining Regulatory Milestone

With this clearance, HeartLung now holds FDA authorization across ten opportunistic screening indications within a single AI platform, positioning AI-CVD® as a foundational technology for population-scale preventive imaging.

As healthcare systems increasingly shift toward early detection, value-based care, and cost containment, AI-CVD® provides a regulatory-cleared pathway to extract far greater clinical value from imaging that already exists—without burdening patients or providers.

About HeartLung.AI

HeartLung Corporation is a medical technology company dedicated to advancing AI-enabled, CT-based opportunistic screening and early disease detection. HeartLung's mission is to shift healthcare from late-stage disease treatment to earlier identification and prevention, using artificial intelligence to unlock clinically actionable information embedded within routine medical imaging.

HeartLung develops FDA-cleared AI technologies for the opportunistic detection and prevention of cardiovascular disease, lung cancer, emphysema/COPD, osteoporosis, myosteatosis, fatty liver disease, and other life-threatening conditions—often years before symptoms appear.

The company has received FDA Breakthrough Device Designation and FDA 510(k) clearance for AutoChamber™, an AI-powered tool that detects enlarged cardiac chambers and left ventricular hypertrophy on non-contrast chest CT scans, including low-dose CT used for lung cancer screening and contrast-enhanced coronary CT angiography (CCTA). HeartLung has also obtained FDA 510(k) clearance for AutoBMD™, the only CT-based, DEXA-equivalent opportunistic osteoporosis screening technology cleared by the FDA and reimbursed by Medicare.

These technologies are now integrated within AI-CVD®, HeartLung's flagship FDA-cleared platform for large-scale opportunistic screening across cardiovascular and multisystem disease domains. By enabling clinicians to extract far greater preventive value from CT scans that are already being performed, HeartLung aims to redefine how imaging contributes to population health, value-based care, and early disease prevention.

For more information, visit https://www.heartlung.ai

About AI-CVD®

The U.S. Food and Drug Administration (FDA) has approved the following Indications for Use for AI-CVD®:

AI-CVD® is an opportunistic, AI-powered quantitative imaging tool that provides automated CT-derived anatomical and density-based measurements for clinician review.Using AI-CVD® quantitative imaging measurements and clinical evaluation, healthcare providers can investigate patients who are unaware of their risk of:

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Stroke

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Aorta and pulmonary artery sizing

Lung attenuation analysis

Liver attenuation analysis

Bone mineral density and muscle–fat composition

Built as a modular, AI-powered quantitative imaging platform, AI-CVD® automatically extracts clinically relevant anatomical and density-based measurements from existing chest and abdominal CT scans—without additional imaging, radiation, contrast, or workflow disruption.

AI-CVD® integrates multiple FDA-cleared technologies, including AutoChamber™ and AutoBMD™, into a unified system designed for opportunistic screening and early disease detection. The platform enables clinicians to identify patients who may warrant additional diagnostic testing, monitoring, or preventive action, using objective, CT-derived measurements from scans that are already being performed for other clinical indications.

Consistent with its FDA-cleared Indications for Use, AI-CVD® does not provide diagnostic interpretation or risk prediction. Instead, it equips healthcare providers with quantitative imaging insights that transform routine CT imaging into a scalable foundation for preventive care across cardiovascular, metabolic, pulmonary, and skeletal disease domains.

Learn more at https://www.heartlung.ai/aicvd

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