



Nanox Receives FDA Clearance for HealthCCSng V2.0, Upgraded Version of Advanced AI Cardiac Solution Empowering Physicians in Assessment of Coronary Artery Calcium

August 21, 2024

HealthCCSng V2.0 introduces additional 'zero calcium' categorization of coronary artery calcium (CAC) and generates a numerical calcium score with corresponding CAC detection category output

Marks second FDA 510(k) clearance of HealthCCSng product

PETACH TIKVA, Israel, Aug. 21, 2024 (GLOBE NEWSWIRE) -- NANO-X IMAGING LTD ("Nanox" or the "Company," Nasdaq: NNOX), an innovative medical imaging technology company, today announced that its deep-learning medical imaging analytics subsidiary, Nanox.AI, received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for HealthCCSng V2.0.

HealthCCSng V2.0 is the upgraded version of Nanox.AI's cardiac solution, HealthCCSng, which has already shown tangible results in several healthcare systems, identifying patients at high risk of coronary artery disease while driving significant revenue to cardiology departments. It has also been seamlessly integrated with existing picture archiving and communication systems (PACS) and electronic medical records (EMR) systems, and enabled timely and appropriate preventive care.

HealthCCSng utilizes medical imaging data from routine non-gated, non-contrast CT scans that include the entire heart of adult patients of ages 30-85 to automatically measure coronary artery calcium (CAC), which is the number one risk predictor for a future cardiovascular event. The product aims to leverage the high utilization of CT scans in the medical care environment, including lung cancer screening programs, to automatically detect calcification in the coronary arteries of patients in an opportunistic manner. Patients with the highest category of CAC levels are over 13 times more likely to suffer a cardiac event.

The device output is available to radiologists as part of their standard workflow. A list of studies that received a successful algorithm analysis result will also be available for further clinical assessment by cardiologists, general practitioners and other medical professionals.

HealthCCSng V2.0 introduces the following features that improve its ability to inform physicians and help them conduct the most appropriate risk assessment and subsequent preventative healthcare for patients:

- **Zero CAC Category:** HealthCCSng now enables clinicians to easily distinguish between patients with zero and low CAC levels. CAC levels of zero are associated with very low risk of cardiac events. The new zero CAC category joins the previously featured 'low', 'medium' and 'high' CAC categories.
- **Numerical CAC Scoring:** HealthCCSng now provides the numerical CAC score alongside the CAC category in its results interface, allowing clinicians to finetune their cardiac risk assessments of patients.
- **CAC Category Configuration:** HealthCCSng now enables users to adjust the lower and upper bounds for the low (1-99 Hounsfield units (HU) by default), medium (100-399 HU by default) and high (400+ HU by default) categories of CAC scores. This added customization allows users to finetune their cardiac risk assessments of patients.

"We are pleased to receive another regulatory clearance from the FDA for our AI cardiac solution, with new updates that reflect our commitment to providing healthcare professionals with the tools they need," said Erez Meltzer, Nanox Chief Executive Officer. "The AI cardiac solution helps to bridge the divide between radiology and cardiology, two medical specialties that often use different terms and descriptions to assess imaging data, and catches patients who might otherwise fall through the cracks so that they can be directed to appropriate preventative healthcare. We will continue exploring opportunities to seamlessly integrate our AI solutions with healthcare systems and clinician workflows, and ultimately enhance patient care and outcomes."

About Nanox.AI

Nanox.AI is the deep-learning medical imaging analytics subsidiary of Nanox. Nanox.AI solutions are developed to target highly prevalent chronic and acute diseases affecting large populations around the world. Leveraging AI technology, Nanox.AI helps clinicians extract valuable and actionable clinical insights from routine medical imaging that otherwise may go unnoticed, potentially initiating further medical assessment to establish individual preventative care pathways for patients. For more information, please visit <https://www.nanox.vision/ai>.

About Nanox

Nanox (NASDAQ: NNOX) is focused on applying its proprietary medical imaging technology and solutions to make diagnostic medicine more accessible and affordable across the globe. Nanox's vision is to increase access, reduce costs and enhance the efficiency of routine medical imaging technology and processes, in order to improve early detection and treatment, which Nanox believes is key to helping people achieve better health outcomes, and, ultimately, to save lives. The Nanox ecosystem includes Nanox.ARC— a multi-source Digital Tomosynthesis system that is cost-effective and user-friendly; an AI-based suite of algorithms that augment the readings of routine CT imaging to highlight early signs often related to chronic disease (Nanox.AI); a cloud-based infrastructure (Nanox.CLOUD); and a proprietary decentralized marketplace, through Nanox's subsidiary, USARAD Holdings Inc., that provides remote access to radiology and cardiology experts; and a comprehensive teleradiology services platform (Nanox.MARKETPLACE). Together, Nanox's products and services create a worldwide, innovative, and comprehensive solution that connects medical imaging solutions, from scan to diagnosis. For more information, please visit www.nanox.vision.

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