UltraSight™ Receives KFDA Regulatory Approval for AI Guidance System, Expanding Global Access to Cardiac Imaging

SEOUL, SOUTH KOREA, June 9, 2025 /EINPresswire.com/ -- UltraSight™, a digital health leader using machine learning to transform cardiac imaging, today announced it has received regulatory approval from South Korea's Ministry of Food and Drug Safety (KFDA) for its real-time machine learning guidance software. The KFDA approval was formally granted to SELVAS Invision, UltraSight™'s joint venture partner in South Korea. This milestone enables UltraSight™ to bring its innovative technology to South Korean clinicians and patients, accelerating the company's mission to expand access to timely, high-quality cardiac care worldwide.

UltraSight™ Logo

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>
> *Davidi Vortman, CEO of UltraSight™*

With this clearance, UltraSight's guidance software is now approved for clinical use in South Korea. The KFDA approval authorizes the use of UltraSight™'s real-time guidance cardiac workflow platform with a range of ultrasound devices to assist medical professionals — regardless of prior sonography experience—in capturing diagnostic-quality cardiac images at the point of care.

"KFDA approval is a pivotal milestone for UltraSight™ as we expand access to critical cardiac imaging tools in one of Asia's most innovative healthcare markets," said Davidi Vortman, CEO of UltraSight™. "By empowering more medical professionals — whether in clinics, emergency departments, or remote settings — to deliver life-saving diagnostics, we're addressing the global disparities in cardiac care. We look forward to partnering with South Korean healthcare teams to make a measurable impact on health outcomes."

UltraSight™'s real-time guidance software is designed to bridge critical gaps in cardiac care by

enabling frontline healthcare workers, emergency responders, and non-specialist physicians to acquire high-quality cardiac ultrasound images—regardless of prior ultrasound experience. This breakthrough expands access to cardiac diagnostics in settings where trained sonographers or cardiologists are not available. The company continues to pursue regulatory approvals for its real-time guidance software in additional global markets.

In parallel with this regulatory milestone, Vortman will present at the upcoming LSI Asia Summit in Singapore. His session, “Echo for Everyone: Accelerating Access to Cardiac Care,” will take place on Thursday, June 12th at 2:40pm SGT. The presentation will explore the urgent global need for scalable cardiac imaging, the AI-powered future of echocardiography, and UltraSight™’s vision of democratizing access to expert-level cardiac diagnostics in Asia, where the burden of cardiovascular disease is rapidly accelerating. This latest milestone marks another step forward in UltraSight™’s mission to put life-saving cardiac imaging in the hands of every healthcare professional globally.

About UltraSight™:
UltraSight™ is revolutionizing cardiac care by enhancing the efficiency and productivity of cardiac ultrasound. Our deep learning based Real-Time Guidance software empowers any healthcare provider to acquire diagnostic-quality echocardiography images, regardless of experience level, optimizing workflows and expanding access to cardiac ultrasound. By democratizing access to cardiac ultrasound, UltraSight aims to improve patient access, operational efficiency, and overall patient care. UltraSight ‘s software has FDA 510(k) and KFDA Clearance and is UKCA and CE Marked to assist medical professionals in performing cardiac ultrasound scans. For more news and information, visit our website or follow UltraSight on LinkedIn and X (Twitter).

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