



## **HealthSeers Announces Strategic Shift to FDA Clearance Phase and Manufacturing for Cairdio Pediatric Heart Screening Technology**

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HealthSeers, Inc., today announced a significant and strategic transition in the development of Cairdio, its proprietary AI-driven pediatric heart screening platform. The company is officially moving beyond its initial prototyping phase and entering the critical stages of formal FDA clearance preparedness and large-scale manufacturing. This milestone marks the successful "graduation" of the technology from its roots in academic research into a robust, market-ready clinical solution. The platform is specifically designed to identify undiagnosed heart murmurs in children, addressing a devastating gap in care that currently leads to over 2,000 pediatric deaths in the United States every year.

To facilitate this complex regulatory transition, HealthSeers has entered into a formal partnership with Proxima CRO. Proxima will manage the comprehensive regulatory journey and provide expert advisory services regarding the quality management system (QMS) essential for securing FDA clearance. This partnership is a proactive step to ensure that as the device enters the medical market, it adheres to the highest possible standards of clinical validation and patient safety.

?We are shifting our focus from proving the concept to preparing for widespread clinical impact,? said Rick Jones, Founder of HealthSeers. ?Working with an industry leader like Proxima CRO is crucial as we navigate the path to FDA clearance. This journey is about ensuring that the 'magic' of our technology is accessible to every pediatrician and parent, moving us beyond the tragedy of the status quo where serious heart conditions often go undetected?.

The timing of this announcement coincides with the successful completion of a series of senior capstone projects conducted in collaboration with the University of Houston and Rice University. These academic partnerships have been fundamental in refining the Cairdio multi-sensor hardware and its breakthrough noise-cancellation capabilities. These engineering advancements allow for highly accurate screenings to be performed in just seconds, maintaining clinical integrity even in the naturally noisy environments of a standard pediatric office.

Looking toward the future, HealthSeers is expanding its clinical evidence base through a collaboration with renowned cardiologist Dr. Asif Ali on an upcoming pilot study and scientific paper. This specialized research, which focuses on the real-world clinical efficacy of the Cairdio platform, is intended for formal submission to the American Heart Association (AHA) Scientific Sessions in November 2026. By integrating advanced AI with a unique hardware design that monitors the heart's main valves simultaneously, HealthSeers is committed to eliminating the risks associated with undiagnosed heart murmurs, ensuring high-fidelity data collection for every child.

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### **HealthSeers, Inc.**

*Cairdio eliminates a massive diagnostic blind spot in pediatric heart health by empowering frontline staff with intuitive, AI-powered technology that detects heart murmurs in seconds - murmurs that stethoscopes miss!*

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