

Category

Best Startup

Product/Solution Name

CardioSignal /Precordior

Date of Approval

2021-04-30

Indications

Detection of atrial fibrillation (CE IIa medical device)(2021)

Patterns of concern and vital signs (FDA listed, 510k Exempt Medical Device)(2023)

Therapeutic Categories

Cardiology

Attached Files:

- ISO27001 Precordior 1321801en.pdf
- ISO27001 Precordior IQ1321801.pdf
- ISO134852016 certificate Precordior.pdf
- CaliforniaMedical Device Manufacturing License.pdf
- EC certificate CardioSignal.pdf

Background information and need for solution/product

We are a medical technology company based on a decade of academic research, developing next generation of digital biomarkers for major common heart diseases. Our patented gyrocardiography technology enables heart disease detection with modern smartphones, no additional hardware needed.

Our patented technology harnesses the sensitive motion sensors of a smartphone to assess heart motion and function. All you need to do is place the smartphone on your chest for 60 seconds. We have today published over 20 peer-reviewed publications on this technology and thousands of patients in our clinical studies. Over 200,000 patients have used the technology in real life home monitoring. Today we have evidence of detection capability for atrial fibrillation, heart failure, aortic stenosis, coronary artery disease and pulmonary hypertension. With this technology, our mission is to transform the field of cardiovascular care by offering an easy access, easy to scale and low-cost solution for screening, monitoring, and diagnosing cardiovascular diseases. Turning a smartphone into a powerful cardiac diagnostic tool has a huge potential to disrupt virtual care models, boost early detection and to decrease the gap in health equity.

Attached Files:

- CardioSignal Gyrocardiography Brochure 3923.pdf
- CardioSignal Intro Brochure.pdf

History of the development of the solution/product

Our technology is based on over a decade of academic research, leading to +20 peer-reviewed publications on the technology and 7 patent families approved to protect the technology. The first robustly validated clinical application for atrial fibrillation detection has been approved as a class IIa medical device in Europe (CE) and in India. In our clinical validation study, we have demonstrated high performance to detect signs of atrial fibrillation: sensitivity 95%, specificity 96%, PPV 96% and NPV 95% (PMID: 29526834).

Our academic collaborators for future of expansion of clinical capabilities include university hospitals in Finland and Stanford University in United States. With these organizations, we have recently concluded studies in heart failure and coronary artery disease. Results from heart failure REFLECS study will be presented in ESC 2023, Amsterdam, and a peer-review publication has been submitted. In our heart failure study with over 1000 patients we demonstrate that a commercially available smartphone powered with CardioSignal solution can perform superior to NTproBNP in heart failure detection.

We have also demonstrated high performance with aortic stenosis for this technology: sensitivity 98.1%, specificity 98.4% and accuracy 98.4% (<https://ieeexplore.ieee.org/document/9662695/>), and we are actively partnering with organizations to further advance its introduction to market.

To date, we have accumulated experience with over 200,000 users that have downloaded the CardioSignal medical device software application on their smartphones for heart health monitoring. This dataset has provided us significant evidence regarding the ease of use in elderly and middle-aged high-risk populations and provided real-life evidence on safety and efficacy of the technology.

In our studies, we have demonstrated that physical characteristics, such as BMI, gender, and underlying lung diseases, do not affect the signal quality, demonstrating that this technology can be widely applied.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

- Significantly expanded diagnostic capability, enabled in at-home monitoring setup
- Compared to other technological solutions requiring additional hardware (wearable devices, medical technology) CardioSignal has the capability to scale aggressively in all layers of the society because smartphones are already distributed widely in society
- Demonstrated ease-of-use in target population of 60+ years of age with significant CVD risk factors, with onboarding possible within 15 minutes from access activation to first measurement
- Is easy to distribute through health systems and remote care providers for both early detection / screening purposes in remote locations as well as utilize it existing remote patient monitoring setups
- Is a powerful tool for clinical trials (existing medication / disease progression studies and as a clinical trial identification tool)
- Represents the most promising way to improve outcomes and lower costs, as early management and preventive actions are significantly more effective at earlier stages of CVDs.

Attached Files:

- CardioSignal Intro Brochure.pdf

Please provide appropriate references (ie Pubmed links)

- Sensors (2022). Koivisto T, Lahdenoja O, Hurnanen T, et al. Mobile Phone Mechanocardiography-Based Measurement System Indicating Changes in Heart Failure Patients during Hospital Admission and Discharge. View publication
- Circulation (2018). Jaakkola et al. Mobile Phone Detection of Atrial Fibrillation Using Mechanocardiography — the MODE-AF Study, Circulation, 2018. View publication.
- IEEE Sensors Journal (2019). M. Jafari Tadi et al., "Comprehensive Analysis of Cardiogenic Vibrations for Automated Detection of Atrial Fibrillation Using Smartphone Mechanocardiograms," in IEEE Sensors Journal, 2019. View publication.
- IEEE Sensors Journal (2019). M. Kaisti et al., "Stand-Alone Heartbeat Detection in Multidimensional Mechanocardiograms," in IEEE Sensors Journal, 2019. View publication.
- IEEE (2018). O. Lahdenoja et al., "Atrial Fibrillation Detection via Accelerometer and Gyroscope of a Smartphone," in IEEE Journal of Biomedical and Health Informatics, 2018. View publication.
- Sci Rep (2018). Iftikhar, Z., Lahdenoja, O., Jafari Tadi, M. et al. Multiclass Classifier based Cardiovascular Condition Detection Using Smartphone Mechanocardiography. Sci Rep 8, 9344 (2018). View publication.
- Sci Rep (2017). Jafari Tadi, M., Lehtonen, E., Saraste, A. et al. Gyrocardiography: A New Non-invasive Monitoring Method for the Assessment of Cardiac Mechanics and the Estimation of Hemodynamic Variables. Sci Rep 7, 6823 (2017). View publication.

Attached Files:

- CardioSignal_PrixGalien.pdf