KardiaMobile 6L offers world’s first FDA-cleared and CE-marked, six-lead personal ECG device based on your smartphone

Slough, 31 August 2019 - AliveCor announced today the European launch of KardiaMobile 6L, the world’s first FDA-cleared and CE-marked, six-lead personal heart monitoring device. This unique, smartphone-based technology provides a multi-dimensional view of the heart in 30-seconds, including visibility into certain arrhythmias, such as atrial fibrillation (AF), that are leading indicators of cardiovascular disease.

“By providing physicians with six different views of the electrical activity of the heart, KardiaMobile 6L offers a much greater chance of detecting a broad range of arrhythmias and other heart conditions than a single lead device,” said Matthew Reed, Consultant in Emergency Medicine, The Royal Infirmary of Edinburgh, NHS Lothian. “If everyone with unexplained heart rhythm symptoms used a pocket-sized heart monitor, it would cut costs, speed diagnosis and avoid preventable hospital admissions.”

AF is the most common arrhythmia, which is a leading cause of AF-related stroke.¹ The incidence and prevalence of AF in Europe is increasing, with approximately 10 million people affected, representing a growing clinical and economic burden.² One in four middle-aged adults in Europe will develop AF,³ and evidence shows that AF-related strokes are more expensive to manage than non-AF-related strokes.¹

“By 2060 it is projected that in Europe nearly 18 million adults over the age of 55 will have AF, making them three to five times more likely to suffer a devastating, debilitating and often fatal AF-related stroke than people without AF,” says Trudie Lobban MBE, Founder and Trustee of the Atrial Fibrillation Association and Arrhythmia Alliance. “Heart rhythm monitoring, coupled with a national screening programme, have the potential to prevent the overwhelming consequences of AF-related stroke and save lives.”

The KardiaMobile 6L is a further development of AliveCor’s existing KardiaMobile® device. In addition to the two electrodes on the top of the device, there is one electrode on the bottom. The user starts a 30 second ECG recording on their smartphone, via the Kardia app, by placing their thumbs on each of the two top electrodes and placing the bottom electrode on their left knee or ankle - enabling the heart to be viewed from six perspectives.

Once a recording has been taken, the artificial intelligence system performs an automatic analysis and informs the patient whether AF, bradycardia (slow heart rhythm), tachycardia (fast heart rhythm) or a normal rhythm is detected. The data collected can then be sent directly to a clinician for further analysis and consultation. Data from a six-lead ECG recording enables clinicians to identify problems that might be undetectable with a single-lead device.

“KardiaMobile 6L is another major milestone in AliveCor’s mission of developing easy-to-use and affordable smartphone-based medical devices,” said Stefan Holzer, VP International, AliveCor Inc. “This innovative device takes heart health management to a new level. The new six-lead technology will significantly broaden the application of personal ECG by providing health care professionals with superior information, potentially allowing for better diagnosis. In combination with our KardiaPro remote monitoring solution, personal ECG monitoring is efficient and cost-effective.”
In Europe, KardiaMobile 6L is available to order from AliveCor resellers across Europe (www.alivecor.com/resellers) and via Amazon.

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Notes to Editors

About AliveCor
AliveCor, Inc. is pioneering the creation of FDA-cleared machine learning techniques and is recognised around the world for transforming cardiac care. The FDA-cleared and CE-marked KardiaMobile is the most clinically validated mobile ECG solution on the market. It is recommended by leading cardiologists and used by people worldwide for accurate ECG recordings. KardiaMobile and KardiaMobile 6L when paired with the Kardia app, provides instant analysis for detecting atrial fibrillation, bradycardia, tachycardia, and normal rhythm in an ECG. Kardia is the first A.I. enabled platform to help clinicians manage patients for the early detection of atrial fibrillation, the most common cardiac arrhythmia and one that leads to a five times greater risk of stroke. The new KardiaPro platform is the only Remote Patient Monitoring platform that works with the existing devices that patients use. AliveCor was named the number one artificial intelligence company on Fast Company's Top 50 Most Innovative Companies, in addition to ranking 20th overall in an evaluation of thousands of companies worldwide. AliveCor owns pending patent applications and issued patents covering ideas presented in this press release including issued U.S. Patent Numbers 9,839,363; 9,572,499; 9,986,925; 9,833,158; 9,351,654; 9,220,430; and 9,579,062. AliveCor is a privately-held company headquartered in Mountain View, Calif. “Consumer” or “Personal” ECGs are ECG devices available for direct sale to consumers. For more information, visit alivecor.com.

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1 Arrhythmia Alliance. White Paper on inequalities and unmet needs in the detection of atrial fibrillation (AF) and use of therapies to prevent AF-related stroke in Europe. Available at; http://www.heartrhythmalliance.org/aa/uk/af-white-paper-2018 (last accessed August 2019).