

Coala Life receives FDA 510k clearance for remote lung auscultation and enhanced ECG algorithm

Coala Life announces today that the US Food & Drug Administration (FDA) has cleared additional indications and uses for the Coala Heart Monitor. The new FDA 510k clearance enables the system to be used for auscultation and monitoring of patients' lungs remotely. The new functionality available is made immediately to existing and new users.

Coala Heart Monitor received its first 510k FDA clearance in 2019. The indication included, among other things, the ability to perform remote smartphone-based ECG with automatic detection of atrial fibrillation and of ability to remotely auscultate the heart.

The new 510k clearance now allows caregivers to use the Coala Heart Monitor and its integrated stethoscope to also monitor and auscultate lungs remotely. The clearance broadens the intended use where the system with its cloud-based care portal can be used by care providers to help detect and monitor various types of lung and respiratory diseases.

"Around 15 million Americans are affected by chronic lung disease (COPD) and the disease mainly affects women. Our new FDA clearance now allows caregivers to use our system to monitor these types of chronically ill patients over longer periods of time in everyday lives. The Coala Heart Monitor now has additional indications within the Remote Patient Monitoring (RPM) reimbursement codes", comments Dan Pitulia, CEO of Coala Life.

The new FDA-clearance also includes an enhanced ECG algorithm for automatic detection of Atrial Fibrillation (AF) based on RR-variability and P-wave analysis.

Since spring of 2020, the Coala Heart Monitor has been temporarily marketed in the United States for lung auscultation with the support of the FDA's temporary regulations 2020-D-1138-0001 applied under Covid-19. Coala Life has now received permanent FDA clearance for this indication and a unique and new respiratory monitoring solution is immediately available to existing and new Coala users in the United States.

About us

Coala Life is a medical device company founded in Sweden focusing on cloud-based cardiac and pulmonary diagnostics. The company has developed and launched the Coala Heart Monitor - a multi-award winning, FDA-cleared and CE-approved product platform enabling long-term remote monitoring, analysis and algorithm-based diagnostics of heart and auscultation of lungs, remote in real-time. The Coala Heart Monitor is mainly marketed to healthcare providers as an Rx solution for use in patient's everyday life and home environment. The company's solutions are based on over 10 years of R&D, and are protected by more than 30 patents. The head office is based in Uppsala, Sweden and since 2019, the US office is based in Irvine, California. More than 10,000 patients have used, been diagnosed or are under long-term monitoring with the Coala Heart Monitor. In the Coala Care Portal, there are currently more than 1,700 doctors and nurses connected to more than 500 care providers. For more information see www.coalalife.com

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Attachments

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