**PRESS RELEASE**

**FDA clears the Coala Heart Monitor**

**Stockholm, Sweden, February 14th, 2019 - Coala Life AB announced today that it has received 510(k) clearance from the Food and Drug Administration (FDA) for the Coala Heart Monitor. The Coala is a novel mobile and cloud based solution with an integrated electrocardiogram (ECG) and digital stethoscope, ideal for remote monitoring of heart conditions. Coala’s algorithms detect for atrial fibrillation (AF) within seconds and the results are instantly available to a connected physician.**

* FDA’s 510(k) clearance of the Coala Heart Monitor is a fantastic milestone and an important performance validation of our unique technology. With CE-approval already in place, millions of heartbeats analyzed and hundreds of healthcare providers connected to our platform, we’re now ready to scale-up into the US market, comments Philip Siberg, CEO of Coala Life.

The Coala Heart Monitor is a Swedish, multiple award-winning, user-centered solution with integrated stethoscope and ECG electrodes avoiding the need of sticky patches, without limits in the time of use and ideal for patient-centered monitoring in everyday life. The Coala analyzes the recordings by use of smart and high-performance algorithms and provides results in seconds.

* Given our success in Northern Europe, we are pleased and proud to be able to offer Americans our innovative digital solution with favorable incentives for the individual, for medical professionals and payors, comments Philip Siberg.

According to the Centers for Disease Control and Prevention (CDC), over 15 million Americans suffer from heart rhythm disorders, of which about one-third suffer from AF. Almost 10% of all Americans over the age of 65 are affected by AF, and many more without knowing it. AF annually leads to about 130,000 deaths in the United States, and the number of people affected is increasing every year.

Cardiac rhythm disorders such as AF are detected and diagnosed by ECG. In 2017 the US market for cardiac arrhythmia monitoring was estimated to be valued in excess of USD 2 billion.

**For more info:**

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**About Coala Life:**

Coala Life is a Swedish digital health venture focused on cardiac diagnostics and digital health. The company has developed a portfolio of patented medical products and services for user-centered digital remote monitoring and screening of the heart based on advanced and smart algorithms. Coala's solutions enable analysis, remote monitoring, more effective cardiac assessments and integrated care services, all in real time. Coala was named one of five global Cool Vendors within the Health and Wellness market by Gartner Group in 2018 and recognized as of the 100 Global Leaders in Digital Health by the Journal of mHealth. Follow your Heart®. For more information see [www.coalalife.com](http://www.coalalife.com)