

Press release (MAR)
Malmö, Sweden November 25, 2020

Acarix receives US market approval for the CADScor® System

Acarix AB (publ) today announced that the US Food and Drug Administration (FDA) has approved the company's De Novo application for marketing approval of the CADScor® System in the US.

"This is a major achievement and a significant recognition of our technology and how it can improve the diagnosis of patients with potential Coronary Artery Disease". "In addition, it will contribute significantly to the value creation of Acarix. This approval enables us to take all measures to prepare the market launch in the USA." said Per Persson, CEO of Acarix".

The De Novo process is used for new products where there is no predicate device with a comparable indication in the US market to support a standard 510 (k) application. Acarix filed the De Novo application in November 2019.

For further information, please contact:

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The information disclosed above is mandatory for Acarix AB (publ) to publish pursuant to the EU Market Abuse Regulation. This information was submitted for publication through the agency of the above contact person on November 25, 2020 at 13:15 am (CET).

About Acarix:

Acarix was established in 2009 and is listed on Nasdaq First North Premier Growth Market (ticker: ACARIX). Acarix's CADScor® System uses an advanced sensor placed on the skin above the heart to listen to the sounds of cardiac contraction movement and turbulent flow. It has been designed to be an all-in-one system in the sense that the heart signal will be recorded, processed, and displayed as a patient specific score, the CAD-score, on the device screen. Readout is obtained in less than 10 minutes. Safe and suitable for use in both out- and inpatient settings, the CADScor® System thus has the potential to play a major role in patient triage, avoiding the need for many patients to undergo stressful invasive diagnostic procedures. Redeye AB (+46 (0)8 121 576 90, certifiedadviser@redeye.se) is Certified Adviser to Acarix. For more information please visit www.acarix.com.