



ASX ANNOUNCEMENT

18 May 2022

FDA Update for CONNEQT Companion App to New Dual Blood Pressure Monitor

Highlights:

- **CONNEQT App has been classified as a Medical Device Data System (MDDS) after submission to the US FDA;**
- **CardieX can now proceed to launch the CONNEQT App, subject to FDA-clearance of the CONNEQT Pulse Dual Blood Pressure Monitor.**

CardieX Limited (ASX:CDX) (**CardieX, the Company**) is pleased to announce that following its recent submission to the US Food and Drug Administration (FDA) for the CONNEQT Companion App (App) (refer ASX, 14 April 2022), the Company has been advised by the FDA that the App has been classified as a non-device MDDS, rather than an accessory to a Class II Medical Device.

As a result, the Company now has the flexibility to launch the App, subject to FDA-clearance of the CONNEQT Pulse.

The MDDS classification of the CONNEQT App provides the Company with flexibility not only when it comes to launching the application, but it also de-risks the pathway to market for CardieX's upcoming new devices, given there will not be a requirement for a full separate submission to the FDA for the consumer companion App.

Approved by the Board of Directors and Released by Jarrod White, Director.

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About CardieX

CardieX is a global health technology company. Its ACTOR subsidiary is a world leader in medical devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders. Its CONNEQT subsidiary develops and markets consumer home health devices and wearables. CardieX is listed on the Australian Stock Exchange (ASX:CDX).