

Friday, May 24, 2024

CamDiab secures FDA approval for advanced adaptive hybrid closed-loop app CamAPS FX

- The Food and Drug Administration (FDA) in the US authorised marketing of CamDiab's CamAPS FX app as an interoperable automated glycaemic controller device on Thursday, May 23
- CamAPS FX is an advanced adaptive hybrid closed-loop app that automatically adjusts insulin delivery on an individual's insulin pump based on their sensor glucose readings
- The FDA authorisation allows the use of CamAPS FX for individuals with type 1 diabetes aged two and older. Additionally, for the first time, the FDA has authorised the use of a closed-loop system during pregnancy
- CamAPS FX is already used by more than 27,000 people in 15 countries across the world

CamDiab has received authorisation from The Food and Drug Administration (FDA) in the US for its advanced adaptive hybrid closed-loop app, CamAPS FX, as an 'interoperable automated glycaemic controller device' (iAGC).

The Android app – known as the world's first artificial pancreas app – helps to manage glucose levels in people with type 1 diabetes, aged two and older, including during pregnancy.

The app allows a compatible insulin pump and a compatible continuous glucose monitor to 'talk to each other', creating an artificial pancreas.

The CamAPS FX closed loop algorithm has been extensively tested in clinical trials and prior to the FDA authorisation on Thursday, May 23, it had already been CE-marked for use in the UK and the EU.

CamAPS FX creator Roman Hovorka is Professor of Metabolic Technology at the Institute of Metabolic Science and Department of Paediatrics at the University of Cambridge, where the technology was developed.

He said: "We set out to help people with type 1 diabetes and their families live better lives and we're delighted that the FDA has reviewed the safety and effectiveness of CamAPS FX and has given the technology its approval.

"It has been extensively tested and we're proud that it is considered by many to be the best algorithm out there.

“Randomised clinical trials have shown a significant increase in time in range and a reduction in HbA1c without increasing the risk of low glucose levels, and improved well-being.”

CamAPS FX is available in Australia, Austria, Belgium, the Czech Republic, Germany, Finland, France, Ireland, the Netherlands, Norway, Poland, Spain, Sweden, Switzerland and the UK and more countries are in the pipeline.

For further information about CamDiab and CamAPS FX, visit <https://camdiab.com/>

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Notes to editors

For further information please email oliver.jelley@ojpr.co.uk or call 07803 003811 or email catherine.bontoft@ojpr.co.uk or call 07759 804793.

About CamDiab

CamDiab Ltd is a digital health and personalised medicine company focused on the design, development, and commercialisation of its world leading, interoperable CamAPS FX closed loop app. The CamAPS FX is designed to use adaptive, self-learning control algorithm, linked to a compatible continuous glucose monitoring device and a compatible insulin pump, to autonomously compute and direct insulin delivery to maintain desired glycaemic levels. Since its founding in 2019, its mission has been to help people with type 1 diabetes and their families live better lives. For further information, visit www.camdiab.com or follow CamDiab Ltd and its products on Facebook, LinkedIn, and X (formerly Twitter) @CamAPS_FX.

