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FDA Approval for First Glucose Monitoring App

Dexcom, Inc. (San Diego, CA) has become the first company to obtain U.S. Food and Drug Administration (FDA) pre-market approval for its mobile apps to support continuous glucose monitoring. The new apps are intended to make it easier for care managers and loved ones to closely monitor glucose levels to avoid complications, such as hyperglycaemia, which can affect the 25.8 million people with diabetes in the U.S. and increase healthcare costs.

Unlike the Dexcom Share charging cradle that the FDA cleared in October 2014, the apps for the Dexcom Share Direct Secondary Displays system allow a lot more flexibility to share data between two iOS network smartphones. The Dexcom Share receiver uses a secure wireless connection via Bluetooth Low Energy (BLE) between a patient's receiver and an app on the patient's smartphone to transmit glucose data to apps on the mobile devices of up to five designated recipients — without the need for a dedicated docking cradle.

This is how the apps work, according to the FDA statement:

Two Dexcom Share System apps display data from its G4 Platinum CGM System, which gets blood glucose readings from a needle with a senor inserted just under the skin of the person being monitored. One app is installed on the patient’s mobile device and the other is installed on the mobile device of another person — a caretaker or loved one. Users can designate who they want to receive the CGM data. The app receives real-time CGM data directly from the G4 Platinum System CGM receiver and transmits it to a Web-based storage location. The caretaker’s app can download the CGM data and display it in real time.

“This innovative technology has been eagerly awaited by the diabetes community, especially caregivers of children with diabetes who want to monitor their glucose levels remotely,” said Alberto Gutierrez, PhD, director of the FDA’s Office of In Vitro Diagnostics and Radiological Health.

The FDA classified the apps as class II devices exempt from pre-market submissions. This means that other manufacturers that want to market devices like Dexcom Share system can skip the process of getting pre-market clearance from the FDA. However, these companies are still required to register and list their device with the agency.

“Exempting devices from pre-market review is part of the FDA’s effort to ensure these products provide accurate and reliable results while still encouraging the development of devices that meet the needs of people living with diabetes and their caregivers,” Gutierrez said.

The FDA also emphasised that the move to approve the apps does not mean they can be a substitute for real-time continuous glucose monitoring or standard home blood glucose monitoring. The apps should not be used to determine diabetes medication dosages either — that has to be done with blood glucose meters, the regulator said.

Diabetes is a chronic metabolic condition where the body is unable to convert glucose into the energy needed to carry out daily activities. If left untreated, high blood glucose levels (hyperglycaemia) can lead to serious long-term problems such as stroke, heart disease, and damage to the kidneys, eyes and nerves.

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Image Credit: Dexcom, Inc.

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