## FDA authorizes DexcomG6 CGM system

**March 30, 2018**—The FDA has granted a de novo request to <u>Dexcom</u> for its Dexcom G6 integrated continuous glucose monitoring system for determining blood glucose levels for people with diabetes ages two and up. This is the first type of CGM system permitted by the agency to be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters, or other electronic devices used for diabetes management. The system is designated a moderate risk, class II medical device and is subject to certain criteria called special controls. With the authorization of the Dexcom G6, future iCGMs that meet the special controls criteria can go through a more streamlined 510(k) clearance process.

"The ability of this device to work with different types of compatible devices gives patients the flexibility to tailor their diabetes management tools to best meet personal preferences," Donald St. Pierre, acting director of the Office of In Vitro Diagnostics and Radiological Health, FDA Center for Devices and Radiological Health, said in a statement. "In addition, the FDA has taken steps to expedite the review process for similar, integrated CGMs and make these types of systems available to patients as quickly as possible while also helping to ensure their safety and reliability."

The Dexcom G6 is a quarter-sized patch device that is applied to the skin of the abdomen and contains a small sensor that continuously measures the amount of glucose in body fluid. The device transmits real-time glucose readings every five minutes to a compatible display device such as a mobile medical app and will trigger an alarm that warns the wearer of pending dangerously high or low blood sugars. If it is integrated with an automated insulin dosing system, a rise in blood sugar would trigger the release of insulin from the pump. It is factory calibrated, does not require users to calibrate the sensor with fingerstick blood glucose measurements, and has an updated sensor probe that minimizes interference with acetaminophen.

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