California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Dexcom, Inc. Dexcom G6, Continuous Glucose Monitoring System

Recall Date	Product Description	Recalling Firm	Recall Reason
02/20/2025	Dexcom G6, Continuous Glucose Monitoring System, REF: STK-OE-001 Dexcom G6, Continuous Glucose Monitoring System, REFs: STK-OM-001, STR-OM-001, STR-OR-001 Dexcom G6, Continuous Glucose Monitoring System, REF: STK-OR-001	Dexcom, Inc.	Under very rare situations, the Dexcom G6 touchscreen receiver may not provide high or low glucose alarms/alerts as designed, which can result in two different conditions. First, if a receiver operating system .net error occurs when an alarm/alert should be triggered, the initial alarm/alert will not be delivered until a subsequent alarm/alert is triggered. At that time, the initial alarm/alert is delivered, but not the second one. Alarm/alerts will continue to be delayed and be one alarm/alert behind, causing delayed alarm/alerts until the receiver is reset. This condition could result in the missed

			detection of a hyperglycemic or hypoglycemic event. Second, a single EGV reading may be delayed for 5 minutes after the initial .net operating system error. If the user receives a single EGV reading delayed by 5 minutes, the delay is not expected to cause user harm.

Recall Class	Product Identification	Distribution	Affected Dates
II	All Serial Numbers UDI: 00386270001900 All Serial Numbers UDI: 00386270000583 All Serial Numbers UDI: 00386270000590	Nationwide including California (software/firmware)	January and prior

For additional information, please visit FDA Website OE-001, FDA Website OM-001, and FDA Website OR-001.