State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Abbott Diabetes Care, Inc. Recalls Component Of The Freestyle Libre 3 Continuous Glucose Monitoring System

Recall Date	Product Description	Recalling Firm	Recall Reason
9/4/2024	**Freestyle Libre 3 Continuous Glucose Monitoring System** FreeStyle Libre 3 Sensors	**ABBOTT DIABETES CARE, INC.** ALAMEDA, CA	Users of the FreeStyle Libre 3 sensors reported situations where they were receiving erroneously high glucose results. The inaccurate higher glucose values may lead to users calculating higher insulin bolus correctional doses based on inaccurate CGM glucose data. The inaccurate higher glucose values may also contribute to missed or delayed recognition of hypoglycemia when the sensor incorrectly reports normal or even high glucose values when the actual glucose is trending low or is low. If the hypoglycemia missed by the device occurs acutely, a user may not be able to confirm the actual glucose with a self-monitored blood

			glucose (BG) and/or administer prompt intervention to raise glucose levels. The over-delivery of insulin and/or the missed or delayed detection of impending or overt hypoglycemia in the worst-case scenario may lead to severe hypoglycemia/hypogl -ycemic crisis with significant adverse health consequences. Such consequences include central nervous system dysfunction, loss of consciousness, seizure activity and may lead to coma, permanent neurological damage, and death.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Freestyle Libre 3 Continuous Glucose Monitoring System** UDI-DI: 00357599818005	8174 Units Nationwide including C	April 2024 and Prior

For additional information, please visit the FDA website.