FDA approves continuous glucose monitoring system

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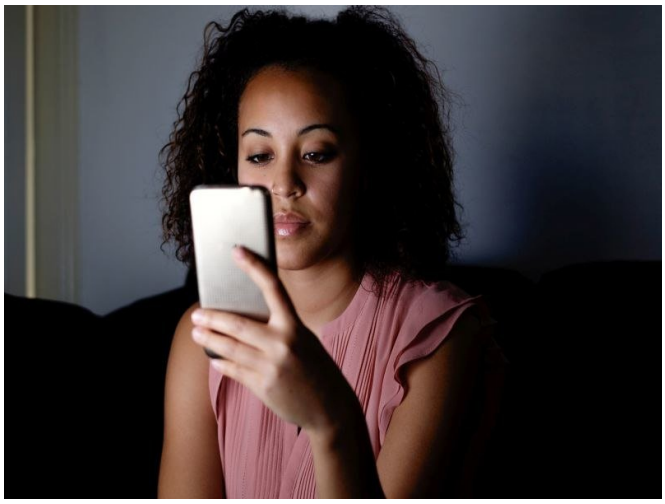

(HealthDay)—The Eversense Continuous Glucose Monitoring (CGM) system, which has a fully implantable sensor to detect glucose, has been approved by the U.S. Food and Drug Administration for use in people age 18 years and older with diabetes.

The Eversense CGM uses a small sensor, which is implanted just under the skin by a qualified health care provider. The sensor regularly measures glucose levels in adults with diabetes for up to 90 days after implantation. The sensor works with a novel light-based technology to measure glucose levels and alerts users via a message sent to a mobile app in cases of hyper- or hypoglycemia.

In order to review the device's effectiveness, the FDA assessed clinical study data from 125 individuals (aged 18 years and older) and compared readings obtained by the Eversense CGM with those obtained by a laboratory-based glucose analyzer. During the clinical studies, the safety of the CGM system's implantable sensor and the procedure used to implant it were also assessed. The proportion of individuals who experienced a serious adverse event was less than 1 percent. Approval of the Eversense CGM System was granted to Senseonics Inc.

"The FDA is committed to advancing novel products that leverage digital technology to improve patient care," FDA Commissioner Scott Gottlieb, M.D., said in a statement. "These technologies allow patients to gain better control over their health."

More information: More Information