Eversense E3 Continuous Glucose Monitoring (CGM) System – P160048/S021

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Eversense E3 Continuous Glucose Monitoring (CGM) System
PMA Applicant: Senseonics, Incorporated
Address: 20451 Seneca Meadows Parkway, Germantown, MD 20876 USA
Approval Date: March 29, 2023
Approval Letter: Approval Order (https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S021A.pdf)

What is it?

The Eversense E3 Continuous Glucose Monitoring (CGM) System provides real-time blood sugar (glucose) values and trends in these levels over time through a mobile app installed on a smart phone, tablet, or other compatible device.

The Eversense E3 Continuous Glucose Monitoring System is a prescription device used to help people with diabetes understand and manage their glucose levels. It can be worn for up to 180 days.

How does it work?

The Eversense E3 CGM includes a small sensor that is implanted under the skin by a doctor. A fluorescent chemical coating on the outside of the sensor generates a small amount of light based on the amount of blood sugar that is present (interstitial glucose).

The light signal is converted into a glucose reading and transmitted wirelessly every five minutes to the user's smart device. The Eversense mobile app lets the user know when glucose values are low or high based on alert settings that are programmed into the app. The system can also alert users when glucose values are approaching potentially dangerously high (hyperglycemic) and/or dangerously low (hypoglycemic) levels. For the Eversense E3 GCM to work properly, the mobile device must be on and fully operational with Bluetooth and notifications for the Eversense mobile app enabled.

The system must be calibrated by testing a fingertip blood sample with a blood glucose meter when prompted. These calibrations are required twice a day for the first 21 days after the sensor is implanted. After that, only one calibration per day is needed unless the system indicates otherwise.

This approval is for the Eversense E3 CGM System that requires one calibration per day more than 99% of the time. Previous approvals were for Eversense E3 CGM systems (P160048/S016 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048S016)) requiring one calibration per day only 62% of the time.

When is it used?

The Eversense E3 CGM System is indicated for use to continually measure glucose levels in adults 18 years and older with diabetes for up to 180 days. The system can also be used in place of fingerstick blood glucose measurements to make diabetes treatment decisions.

What will it accomplish?

People with diabetes can use the information from this device to make treatment decisions, including when to give insulin or

carbohydrates. The system is intended to provide real-time glucose readings, glucose trend information, and alerts that predict hypoglycemia and hyperglycemia. Historical data from the system can be help providers and patients make treatment plans and adjustments that will keep blood glucose levels in a safe range. These adjustments should be based on the patterns and trends seen over time.

When should it not be used?

The Eversense E3 CGM's Smart Transmitter is not magnetic resonance imaging (MRI) compatible and must be removed before an MRI. Additionally, the system should not be used in people who cannot tolerate the corticosteroid dexamethasone (https://medlineplus.gov/druginfo/meds/a682792.html) or dexamethasone acetate.

Eversense users should also be aware that some sugar alcohols (mannitol and sorbitol) used in healthcare settings and given through the blood vessels (intravenously) or as a part of an irrigation or peritoneal dialysis (https://medlineplus.gov/ency/article/007434.htm) solution, may cause a false high glucose result from the system's sensor. However, sorbitol levels in artificial sweeteners that are used as part of a typical diet do not impact sensor glucose results.

Additional information (including warnings, precautions, and adverse events):

- Summary of Safety and Effectiveness Data (SSED) (https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S021B.pdf)
- Labeling (https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S021C.pdf)
- PMA Database entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048S021)

Was this helpful? Yes No