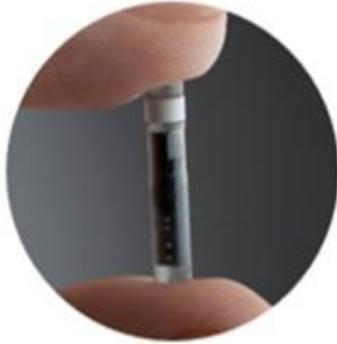# Eversense E3 Continuous Glucose Monitoring System - P160048/S016

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 Montioring System
PMA Applicant: Senseonics, Inc.
Address: 20451 Seneca Meadows Parkway, Germantown, MD 20876
Approval Date: February 10, 2022
Approval Letter: Approval order
(https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S016A.pdf)

What is it?

The Eversense E3 Continuous Glucose Monitoring (CGM) System gives real-time blood sugar (glucose) readings every five minutes for people with diabetes. The system consists of an implantable fluorescence-based sensor, a transmitter, and a mobile app for displaying glucose values, trends and alerts on the patient's compatible mobile device (smart phone, tablet, etc.).

This approval allows for the new version of the sensor to be worn for up to 180 days. Previous versions of the sensor were approved by the FDA for only 90 days of wear.

How does it work?

A doctor implants a sensor under a person's skin to monitor how much sugar (glucose) is present in the fluid under the skin. A wireless transmitter worn outside the body takes the sensor's information and uses Bluetooth to send the glucose reading to the Eversense mobile

app on the user's mobile device every 5 minutes. The Eversense mobile app can also alert the user when glucose readings are too high (hyperglycemia) or low (hypoglycemia) based on alert settings programmed by the user. For the Eversense E3 CGM System to function properly, the mobile device must be on and fully operational with Bluetooth enabled and notifications for the Eversense mobile app enabled. The system must be calibrated 1-2 times per day by testing a fingertip blood sample with a blood glucose meter.

When is it used?

The Eversense E3 CGM System is intended to measure glucose levels in people 18 years and older who have diabetes. The sensor can be worn under the skin continually for up to 180 days. It is intended to replace the fingerstick blood glucose measurements that are traditionally used to help make treatment decisions for diabetes.

What will it accomplish?

People with diabetes can use the information provided by the Eversense E3 CGM System to make daily diabetes treatment decisions, such as when to take insulin or carbohydrates. It can also alert users when glucose values are approaching potentially dangerously high and/or dangerously low levels. The data collected by the system can track long-term trends in glucose measurements and help patients and their providers make adjustments to treatment plans over time to keep blood glucose levels in a safe range.

When should it not be used?

The Eversense E3 CGM System should not be used by:

- People who cannot have corticosteroids dexamethasone or dexamethasone acetate.

Additionally, the following procedures should not be done on people who have the Eversense E3 CGM System implanted:

- MRI: The smart transmitter is not compatable with magnetic resonance imaging (MRI) and must be removed before any MRI procedure.

- Lithotripsy: The use of lithotripsy (a treatment that typically uses ultrasound shock waves to break up masses like kidney stones or gallstones) is not recommended for people who have an inserted sensor because the effects are unknown.

- Diathermy: Diathermy (the generation of heat using electrical pulses) should not be used on people with an inserted sensor, because energy from diathermy therapy can transfer through the sensor and cause tissue damage in the insertion area.

- Electrocautery: The use of electrocautery (a heated electrode applied to living tissue to stop blood flow or destroy tissue) near an inserted sensor may damage the device.

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

- Labeling (https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S016C.pdf)

- Summary of Safety and Effectiveness Data (https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S016B.pdf)

- PMA Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048S016)