SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Sensor, Glucose, Invasive, Component of automated insulin delivery system

Device Trade Name: Simplera Sync Sensor
Guardian 4 Sensor

Device Procode: SFI

Applicant's Name and Address: Medtronic MiniMed, Inc.
18000 Devonshire Street
Northridge, CA 91325

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P250012

Date of FDA Notice of Approval: August 6, 2025

The PMA under P250012 references previously approved PMA submissions for Medtronic automated insulin dosing (AID) systems. The original PMA for the MiniMed 670G system (P160017) was approved on September 28, 2016, for use in persons ages 14 years and older. PMA Panel Track Supplement P160017/S091, approved on April 21, 2023, introduced the MiniMed 780G System, added the Advanced Hybrid Closed Loop (AHCL) algorithm, and added compatibility with the Guardian 4 Continuous Glucose Monitor (CGM) for use in persons ages 7 years and older. PMA panel track supplement P160017/S118 was approved on April 18, 2025 and added compatibility to the Simplera Sync CGM as an alternative CGM component for the 780G system in addition the Guardian 4 Sensor and also updated the AHCL algorithm to modify the calculation of auto correction boluses and daily user adaptations. The SSEDs that support the use of the Guardian 4 Sensor and Simplera Sync CGMs as inputs for the AHCL algorithm within the 780G system are available in the FDA Premarket Approval database and are incorporated here by reference.

The purpose of this PMA is to establish an independent marketing authorization for the two Medtronic CGM sensors that can serve as input devices for compatible Medtronic automated insulin dosing (AID) systems. These sensors may also be used as input devices for future Medtronic AID systems after appropriate verification and validation activities, as determined by FDA.

II. INDICATIONS FOR USE

Simplera Sync Sensor

The Simplera Sync sensor is a continuous glucose monitor (CGM) intended for use with compatible Medtronic automated insulin dosing (AID) systems to monitor glucose levels for the management of diabetes.

The Simplera Sync sensor is not intended to be used directly to make therapy adjustments while the AID system is operating in manual mode. All therapy adjustments in manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Simplera Sync sensor.

The Simplera Sync sensor is indicated for persons 7 years and older for insertion in arm.

The Simplera Sync sensor is intended for single use and requires a prescription.

The Simplera Sync sensor can be used one time and has a life of up to 6 days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first 6 days, to allow the patient to change their sensor more flexibly.

The Simplera Sync sensor is indicated for the management of diabetes in persons ages 7 years and older.

Guardian 4 Sensor

The Guardian 4 sensor is intended to monitor glucose levels for the management of diabetes for persons ages 7 years and older. It is indicated for use as an adjunctive device to complement, not replace, information obtained from the standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian 4 sensor is indicated for up to 7 days of continuous use. Refer to the system user guide for treatment decisions.

The Guardian 4 sensor continuous glucose monitor (CGM) is also intended for use with Guardian 4 Transmitters and compatible Medtronic automated insulin dosing (AID) systems to monitor glucose levels for the management of diabetes.

The Guardian 4 sensor is not intended to be used directly to make therapy adjustments while the AID system is operating in manual mode. All therapy adjustments in Manual mode should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian 4 sensor.

The Guardian 4 sensor is indicated for persons 7 years and older for insertion in arm.

The sensor is intended for single use and requires a prescription.

Guardian 4 Transmitter
The Guardian 4 transmitter is intended for use with Guardian 4 sensors and compatible Medtronic automated insulin dosing (AID) systems to monitor glucose levels for the management of diabetes.

III. CONTRAINDICATIONS

There are no contraindications listed in the labeling.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Simplera Sync sensor and Guardian 4 sensor labeling.

V. DEVICE DESCRIPTION

Simplera Sync Sensor
The sensor is a sterile, all-in-one glucose sensing device, intended as a single patient, single-use component of a personal CGM system for the management of diabetes in persons 7 years of age and older. The Simplera Sync sensor can be used one time and has a life of up to six days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work as it did during the first six days, to allow the patient to change their sensor more flexibly. The sensor calculates user glucose concentrations based on collected signals from the interstitial fluid and transmits glucose and device data to the networked device. It is intended to replace fingerstick blood glucose (BG) readings for treatment decisions and reduce the overall burden associated with diabetes management.

Guardian 4 sensor
The Guardian 4 sensor is a sterile, single-use, single patient glucose sensing component for continuous monitoring of glucose levels in the user's interstitial fluid for up to seven days. The Sensor is inserted into the subcutaneous tissue using the One-Press Serter and is taped to the user's skin. It connects to the Guardian 4 transmitter, which in turn communicates with a compatible Medtronic AID system.

Guardian 4 transmitter
The Guardian 4 transmitter is a portable, electrical current meter intended to process, store, and transmit glucose sensor values to the compatible Medtronic AID system. The transmitter sends sensor glucose (DG) values and sensor integrity (SI) data from the Guardian 4 sensor to the compatible Medtronic AID system via BLE wireless communication protocol. The Guardian 4 transmitter does not require entry of fingerstick blood glucose measurement for calibration purposes.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Control of diabetes can be achieved through a combination of various behaviors and methods.

Self-behaviors including healthy eating, taking the clinically indicated medications (pharmaco-vigilance), and being physically active are fundamental lifestyle activities that are important for achieving glycemic control regardless of the methods of monitoring glucose and insulin administration.

Methods of monitoring glycemic control include periodic measurement of Hemoglobin A1c (HbA1c) which reflects mean blood levels control over a three-month period. This test is ordered and interpreted by the person with diabetes' (PWDs) healthcare provider. Self-monitoring of blood glucose using glucose meters and test strips provides quantitative measurements of blood glucose at a single point in time for PWDs and their healthcare providers. This helps to monitor the effectiveness of glycemic control, as well as in making more immediate treatment modifications.

PWDs may administer insulin by injection or using other insulin infusion pumps as prescribed by their physician. An insulin pump is an alternative to multiple daily insulin injections (via insulin syringe or an insulin pen). There are currently several commercially available ambulatory insulin infusion pumps that can be used for insulin infusion. Additionally, sensor-augmented insulin infusion pumps or continuous glucose monitoring systems may be used to record continuous interstitial glucose information and provide real-time hypoglycemia and hyperglycemia alerts. Several available insulin pump systems offer automated features where insulin delivery may be suspended when sensor glucose has reached or is predicted to reach a user selected low glucose threshold. Hybrid closed loop insulin pump systems are also available for people with type 1 diabetes. These systems can automatically increase or decrease the amount of insulin delivered to maintain glucose within an optimal range.

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

A prior version of the Simplera Sync sensor was approved under P160017/S118 as a component of the MiniMed 780G system, and as of the writing of this document has not yet been marketed in the United States.

A prior version of the Guardian 4 sensor was approved under P160017/S091 as a component of the MiniMed 780G system, and has been available in the United States since May 2023.

These devices have not been withdrawn from commercial distribution for any reason related to either safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the Simplera Sync sensor and Guardian 4 sensor CGM systems.

Potential adverse effects related to sensor use include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where the sensor was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage, or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive, tapes, or both
- Scarring

There are potential adverse effects associated with using these CGMs in an AID system when they provide inaccurate measurements or rate of change values, as follows:

The risks of an AID system making dosing decisions based on falsely high readings include inappropriate or excessive administration of insulin. These inappropriate treatments could increase the risk of hypoglycemia or prolong existing hypoglycemia which can result in seizures, loss of consciousness, and rarely, death.

The risks of an AID system making dosing decisions based on falsely low readings include inappropriate administration of carbohydrates. These inappropriate treatments could increase the risk of hyperglycemia or prolong existing hyperglycemia, increasing exposure to long-term microvascular complications of diabetes (eye, kidney, nerve and heart disease) and acute diabetic ketoacidosis (DKA) which can result in weakness, seizures, and death.

The risks of an AID system making dosing decisions based on inaccurate calculation of the rate of change of glucose could increase the risk of serious hypoglycemia or hyperglycemia if treatment is influenced by the inaccurate rate of change. Inaccurate calculation of the rate of change of glucose could also prevent a patient from taking measures to prevent a sustained increase or decrease in glucose levels, which could lead to serious hypoglycemia or hyperglycemia.

There are potential risks associated with making acute and long-term therapy adjustments when glucose values and rates of change provided by the device are inaccurate. The risks of making therapy adjustments based on inaccurate device information include inappropriate adjustment of diabetes medication regimens. This could increase the risk of hypoglycemia and corresponding risk of seizures, loss of consciousness, and rarely, death; it may also increase the risk of hyperglycemia, increasing exposure to long-term microvascular complications of diabetes (eye, kidney, nerve and heart disease) and risk of DKA which can cause weakness, seizures, and death.

For the specific adverse events that occurred in the clinical studies that used these sensors as inputs to an AID system, please see the SSEDs for P160017/S091 and P160017/S118.

IX. SUMMARY OF NON-CLINICAL STUDIES

There is no new non-clinical study information provided in the submission or used to assess the safety and effectiveness of the subject device.

All prior non-clinical studies from P160017/S118, P160017/S091, and P160007/S047 are unchanged and are leveraged for P250012 to support safety and effectiveness. For example, prior non-clinical information includes human factors validation studies, software verification and validation, cybersecurity penetration testing, electromagnetic compatibility testing, reliability testing, electrical safety testing, and others.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

No new clinical studies were conducted to support the change in the indications for the device. The applicant previously performed clinical studies to establish that the Simplera Sync sensor (G200156) and Guardian 4 sensor (G190075 and G190047) are safe and effective when used as inputs to the MiniMed 780G System. Summaries of the results of these prior clinical studies are provided in the SSEDs for P160017/S118 and P160017/S091, respectively.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. There was no new clinical data

submitted and therefore there are no new financial disclosures. Refer to the SSEDs for P160017/S118 and P160017/S091 for previously provided financial disclosure information. The information previously provided does not raise any questions about the reliability of the data.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA Supplement was not referred to the Clinical Chemistry and Toxicology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

There have been no design changes to the Simplera Sync sensor or Guardian 4 sensor since P160017/S118 and P160017/S091 that approved the sensors for use with the MiniMed 780G system. The only significant changes in this submission were to the indications for use to indicate that the Simplera Sync sensor and Guardian 4 sensor are intended for use with compatible Medtronic AID systems. This change does not affect the conclusions drawn from preclinical studies, clinical studies, and patient perspectives as described in the SSEDs for P160017/S118 and P160017/S091.

XIV. CDRH DECISION

CDRH issued an approval order on August 6, 2025.

The applicant's manufacturing facilities have been previously inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

None