SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Automated Insulin Delivery System

Device Trade Name: MiniMed 670G System

Device Procode: OZP, Artificial pancreas device system, single hormonal control

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: P160017/S017

Date of FDA Notice of Approval: February 13, 2018

Priority Review: Not Applicable

The original PMA (P160017) was approved on September 28, 2016 and is indicated for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication for the Guardian Sensor (3) by adding the upper arm as an approved insertion site for the sensor.

II. INDICATIONS FOR USE

MiniMed 670G System
The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin(at user selectable rates) and administration of insulin boluses (in user selectable amounts)for the management of Type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G System includes SmartGuard technology,which can be programmed to automatically adjust delivery of basal insulin based onContinuous Glucose Monitor sensor glucose values, and can suspend delivery of insulinwhen the sensor glucose value falls below or is predicted to fall below predefined threshold values.

The Medtronic MiniMed 670G System consists of the following devices:
MiniMed 670G insulin pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter. The system requires a prescription.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

Guardian Sensor (3)

The Guardian Sensor (3) is intended for use with the Medtronic MiniMed 630G and MiniMed 670G systems to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trendsand tracking patterns in persons aged fourteen years and older, and to be used by theMiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use asan adjunctive device to complement, not replace, information obtained from standard bloodglucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use.

One-press Serter

The One-press Serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use.

Guardian Link (3) Transmitter

The Guardian Link (3) Transmitter is intended for use with the MiniMed 670G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use.

Contour NEXT Link 2.4 Glucose Meter

The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for themeasurement of glucose in whole blood, and is for single patient use only and should not be shared. The Contour Next Link 2.4 wireless blood glucose monitoring system is indicatedfor use with fresh capillary whole blood samples drawn from the fingertip and palm only.
The Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The Contour Next Link 2.4 wireless blood glucose monitoring system is intended to be used to transmit glucose values to the MiniMed 670G pump and facilitate transfer of information to Medtronic CareLink Software through the use of radio frequency communication. The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for, diabetes mellitus. It is not intended for use on neonates.

III. CONTRAINDICATIONS

A prominent boxed warning is included in the labeling regarding use of the device in subjects under the age of 7 years as follows:

"Medtronic performed an evaluation of the 670G closed loop system and determined that it may not be safe for use in children under the age of 7 because of the way that

the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day becausethe device requires a minimum of 8 units per day to operatesafely."

The following contraindications for this device are also described in the labeling:

- Insulin pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day. As insulin pumps use rapid acting insulin only, blood glucose testing is required to help identify rapid glycemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination ofthese.
- Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.
- Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.
- Do not use serter on products other than the Enlite Sensor (P120010) or Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.
- The reservoir is contraindicated for the infusion of blood or blood products.
- Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the MiniMed 670G System labeling.

V. DEVICE DESCRIPTION

There is no physical change to the MiniMed 670G System as a result of this panel track supplement. The MiniMed 670G system is comprised of the following devices:

MiniMed 670G Pump (MMT-1780)

The MiniMed 670G pump (model MMT-1780) is an ambulatory, battery operated, rate programmable micro infusion pump designed to deliver insulin from a reservoir. The reservoir is driven by a motor to deliver determined basal rate profiles and user selected bolus amounts of insulin into the subcutaneous tissue through an infusion set.

In addition to its delivery of insulin, the MiniMed 670G pump is designed to receive and display real-time interstitial fluid glucose values via the Guardian Link (3) Transmitter. When used in combination with Guardian Sensor (3), the transmitter sends sensor signals to the MiniMed 670G pump via radiofrequency (RF) telemetry. The 670G Pump has the following features and capabilities:

- Provides predictive sensor glucose alerts when sensor glucose values are high or low (please see 'Manual Mode' section below for details).
- Can receive blood glucose values from the Contour NEXT Link 2.4 Meter to use

for sensor calibration.

- The pump can display Guardian sensor glucose values in real-time, and store those values (blood-glucose values from the meter) into its pump memory.
- "SmartGuard" Technology: There are two levels of this technology; the first is available in Manual Mode and the second in Auto Mode.
    - The first level of SmartGuard technology is available in Manual Mode:
        - This technology automatically suspends insulin when the sensor reaches a preset low limit (referred to as 'Suspend on Low')
        - This technology automatically suspends insulin when the sensor glucose value is predicted, using a proprietary predictive suspend algorithm, to reach a pre-set low limit, i.e., suspends before the low limit is reached (referred to as 'Suspend before Low').
        - When a Suspend event occurs, the user can choose to continue to keep insulin suspended, or the user can choose to resume insulin delivery.
        - Following a Suspend event, insulin delivery will automatically resume when the sensor glucose levels rise above the pre-set suspend threshold.
        - The 'Suspend on low' and 'Suspend before low' features are optional features available when the system is in Manual Mode.
        - This technology (in Manual Mode) provides a bolus calculator called the 'Bolus Wizard' that uses your settings to calculate an estimated bolus amount based on the meter blood glucose values and carbohydrates that the user enters. These settings should be set up with the help of a Health Care Practitioner before using the Bolus Wizard. Those settings include:
            - Carbohydrate Ratio
            - Insulin Sensitivity Factor
            - Blood Glucose Target
            - Active Insulin Time

    - The second level of SmartGuard technology is available in Auto Mode:
        - This technology automatically adjusts basal insulin delivery using continuous glucose monitor data, referred to as Auto Mode.
        - The Auto Mode feature can automatically increase or decrease the amount of insulin delivered based on sensor values.

During Auto mode operation, the user must manually deliver meal boluses that they calculate using the estimated amount of carbohydrates for meals at the time they are eaten. The user must also use the Auto Mode bolus feature to calculate boluses while in Auto Mode.

Guardian Link Transmitter System (MMT-7811)

The Guardian Link Transmitter System consists of the Guardian Link Transmitter (MMT-7811), the Charger (model MMT-7715), and the Tester (model MMT-7736).

The Guardian Link Transmitter interfaces directly with the glucose-sensor assembly. The Guardian Link Transmitter provides power to the glucose sensor, and measures the sensor signal current from the glucose sensor.

The sensor signal current is an electrical current level that is proportional to the glucose level in the user's subcutaneous interstitial fluid. The sensor signal current is converted to a digital signal, which is filtered to reduce noise artifacts. This digital signal is sent to the MiniMed 670G pump every 5 minutes, using radio frequency (RF).

Guardian Sensor (3) (MMT-7020)

The Guardian Sensor (3) is a sterile, single-use, single patient glucose sensing component for continuous monitoring of glucose levels in the user's interstitial fluid, when inserted in the user's abdomen or arm 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 Link Transmitter, which in turn communicates with the MiniMed 670G Pump. Though originally approved (P160017) for insertion into the abdomen only, in this supplement the sensor is now approved for insertion into the upper arm in addition to the abdomen.

When making treatment decisions, such as determining insulin dose for meals, the 670G continuous glucose monitor (CGM) values should not be used, as they are not intended to be used to make such treatment decisions. The 670G continuous glucose monitor does not replace a blood glucose meter. Users should always use the values from a blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose values. Using the sensor glucose readings for treatment decisions could lead to unwanted high or low blood glucose.

Users should calibrate the Guardian Sensor at least every 12 hours using meter blood glucose values. Calibration is necessary for sensor function, and more frequent calibration can help to increase the accuracy of the sensor. The system requires a minimum of two calibrations per day, and four calibrations per day are recommended. The system is contraindicated for patients unwilling or unable to do frequent blood glucose meter measurements.

If the user obtains blood glucose values using the Contour Next Link 2.4 Meter, the user may transmit blood glucose values via Bluetooth to the 670G pump to be used for sensor calibrations. If the user uses a different FDA cleared blood glucose meter to calibrate the Guardian Sensor, the user must manually input the blood glucose values into the pump to be used for sensor calibration. Additionally, users who use the Contour Next Link 2.4 should calibrate with values obtain using fingersticks; users should not use readings obtained from blood from alternative sites (e.g., palm).

One-Press Serter

The One-Press serter is a sensor insertion device which aids the user in inserting the Guardian Sensor. The serter was also previously reviewed and approved under P120010/S070. The user must use the One-Press Serter in order to insert the Guardian

Sensor.

Contour Next Link 2.4 Meter (MMT-1352 and MMT-1152) and Test Strips

The Contour Next Link 2.4 Meter can be used with the 670G system; the meter wirelessly sends blood glucose values to the insulin pump for sensor calibration via Bluetooth. The meter was also previously cleared under k110894. Specifications and performance requirements were established for the meter and evaluated as part of the class III 670G System.

Additional System Accessories

The following additional accessory devices are compatible with the 670G Insulin Pump (Table 1):

Table 1: Accessory Devices

Device	Model
Reservoirs and Infusion Sets	**Model Numbers**
MiniMed Quick Set Infusion Set	MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399
MiniMed Silhouette Infusion Set	MMT-368, MMT-369, MMT-370, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384
MiniMed Mio Infusion Set	MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-965, MMT-975
MiniMed Sure-T Infusion Set	MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-886
Paradigm Reservoir	MMT-332A
Optional Devices	**Model Numbers**
CareLink USB 2.4	MMT-7306
CareLink Online (Personal)	MMT-7333
CareLink Pro	MMT-7335

VI. ALTERNATIVE PRACTICES AND PROCEDURES

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

Self-behaviors include healthy eating, taking the clinically indicated medications, and being active. Persons with diabetes may also 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). Periodic self-glucose monitoring using home use blood glucose meters provides information regarding variations in glucose levels.

Methods of monitoring glycemic control include periodic measurement of Hemoglobin A1c (HbA1c) which reflects blood glucose control over a three-month period. Self-monitoring of blood glucose using glucose meters and test strips provides quantitative

measurements of blood glucose at a single point in time for users and their healthcare providers. This helps to monitor the effectiveness of glycemic control, as well as make more immediate treatment modifications.

Currently, cleared or approved insulin infusion pumps may be used for continuous subcutaneous insulin infusion. Additionally, commercially available 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.

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

VII. MARKETING HISTORY

The MiniMed 670G System was approved for marketing in the United States in September 2016. The device has not been withdrawn from marketing for any reason related to its 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 device.

- Diabetic ketoacidosis (DKA) resulting from high blood glucose due to suspension of insulin delivery or inadequate insulin delivery (which may result from catheter occlusion, hardware or software malfunction, erroneous CGM readings in Auto Mode or suspend mode, or inadequate insulin dosing).
- Severe hypoglycemia resulting from over-delivery of insulin (which can result from hardware or software malfunction, erroneous CGM readings in Auto Mode, or erroneous insulin dosing), which may lead to seizure, unconsciousness, and rarely death.

Potential device related non-serious events include:

- Skin irritation or redness
- Infection
- Pain or discomfort
- Bruising
- Edema
- Rash
- Bleeding
- Induration of skin
- Allergic reaction to adhesives

Sensor breakage with fragments retained under the skin is a potential adverse event related to use of the CGM component of the 670G system, but this was not observed during these

studies. Based on postmarket experience with similar devices and the results observed in these clinical studies, the occurrence and severity of these events is low.

Infection at the insulin pump infusion set insertion site and sensor insertion site is a potential complication related to insertion of the CGM or the insulin pump infusion set. Based on post-market experience with similar devices, and the results observed in these clinical studies, the occurrence and severity of these events are not expected to be different from other approved infusion sets and CGM devices.

Use of insulin pumps are known to carry an increased risk of DKA. However, FDA has received information indicating some patients are willing to accept an increased risk of DKA or ketosis and hyperglycemia (severe hyperglycemia) because of the benefits of pump use (see also Section XII below).

Like other insulin pumps, there is an inherent risk that users of the device who do not use the 670G device as intended could harm themselves. Therefore, the device is for prescription use only and contraindicated for people unwilling or unable to perform a minimum of four fingerstick blood glucose meter tests per day and for people unwilling or unable to maintain contact with their healthcare professional.

There is a theoretical risk of insulin over-delivery due to device malfunction which has a risk of leading to severe hypoglycemia due to malfunction of the 670G System. This event did not occur during the pivotal study or the continuation phase of the pivotal study. If insulin over-delivery were to occur, there are several mechanisms in place designed to help detect and mitigate the risk of impending and/or current hypoglycemia, including the presence of alarms/alerts and the suspension/reduction of insulin delivery.

There is a theoretical risk of insulin under-delivery (due to a hardware or software malfunction) which may lead to severe hyperglycemia or DKA due to malfunction of the 670G system. This event did not occur during the pivotal study or the continuation phase of the pivotal study. If insulin under-delivery were to occur, there are mechanisms in place to help detect impending and/or current hyperglycemia, including the presence of alerts and alarms.

The consequences of falsely high glucose reading on the continuous glucose monitor would be potential over-delivery of insulin via automated insulin delivery and missed low glucose suspensions and alerts/alarms, which have the potential to lead to severe hypoglycemia. The consequences of falsely low glucose reading on the continuous glucose monitor would be potential under-delivery of insulin and missed high glucose alerts, which have the potential to lead to severe hyperglycemia or DKA.

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

Please see the SSED for P160017 for descriptions of the pre-clinical testing of the MiniMed 670G system and components.

B. Animal Studies

None.

C. Additional Studies

None.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

Medtronic conducted a study to evaluate the performance of the Guardian Sensor (3) to support a full 168 hours (7 days) of use under IDE # G140053. This study included evaluation of sensors inserted into both the abdomen and the upper arm and served as the primary clinical study for this Panel Track Supplement. A summary of the clinical study is presented below.

A. Study Design

The data submitted in support of this Panel Track Supplement was collected between April 30, 2015 and August 25, 2016 and included 89 patients. There were 6 investigational sites.

This study was a multi-center, prospective, single-sample correlational study without a control group, designed to determine the performance of the Guardian Sensor (3) in adolescents and adults with Type I or Type II Diabetes Mellitus between the ages of 14-75 years. All subjects wore two CGMs in the abdomen and one CGM in the upper arm. One of the abdomen CGM consisted of a Guardian Sensor (3) (also referred to as the Guardian sensor below) connected to the Guardian Link (3) transmitter, which transmitted to the insulin pump (for display purposes only). The other abdomen CGM used the Guardian Sensor (3) connected to a transmitter with the same real-time algorithm as the Guardian Link (3) transmitter, which transmitted to a display device. The CGM sensor worn in the upper arm was connected to a recording device. Data from the arm sensor was downloaded at the end of the study and reprocessed using the same real-time algorithm as the abdomen sensors.

Subjects wore the Guardian sensor for a 7-day training period (that included a minimum 6 days of sensor wear), followed by a 7-day study period. During the study period, each subject participated in three in-clinic, frequent sample testing interventions. Frequent sample testing occurred at the beginning (Day 1), middle (Day 3) and end (Day 7) of the Guardian sensor system use. During these FST sessions, intravenous (IV) blood samples were drawn every 5 to 15 minutes and analyzed for plasma blood glucose levels using the comparator method (CM). The CM is this study was the Yellow Springs Instrument 2300 Stat Plus Glucose Lactate Analyzer. Frequent sample testing with the CM lasted approximately 12 to 14 hours during the in-clinic visit.

Subjects were randomized to one of 2 groups that determined when they participated in the in-clinic frequent sample testing; a day cohort (hours 1-12) and an evening cohort (hours 12-24).

Subjects continued with their current diabetes regimen independent of the study devices. Subjects were instructed by the investigational center that they were not to use the investigational devices for the management of their diabetes.

There was no control group as this study was an observational study to determine the accuracy and precision of the Guardian sensor. Accuracy was assessed by comparing the sensor values to the CM, and precision of the sensor system was assessed by comparing sensor values from the arm to the sensor values in one abdomen sensor for each subject.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Guardian sensor study was limited to subjects who met the following inclusion criteria:

   1. Subject is 14 - 75 years of age at time of screening
   2. A clinical diagnosis of type 1 or 2 diabetes for a minimum of 12 month duration, as determined via medical record or source documentation by an individual qualified to make a medical diagnosis
   3. Adequate venous access as assessed by investigator or appropriate staff
   4. Subjects participating in the high and low glucose challenges must have an established insulin: carbohydrate ratio(s) and insulin sensitivity ratio. (The term "established" refers to a ratio that has been previously defined and tested prior to screening visit). Subjects without established ratios may be enrolled but will not be subjected to high and low glucose challenges.

   Subjects were not permitted to enroll in the Guardian sensor study if they met any of the following exclusion criteria:

   1. Subject will not tolerate tape adhesive in the area of Guardian Sensor placement as assessed by qualified individual
   2. Subject has any unresolved adverse skin condition in the area of Guardian Sensor or device placement (e.g., psoriasis, rash, *Staphylococcus* infection)
   3. Subject is actively participating in an investigational study (drug or device) wherein they have received treatment from an investigational study (drug or device) in the last 2 weeks
   4. Subject is female and has a positive pregnancy screening test
   5. Females of child bearing age and who are sexually active should be excluded if they are not using a form of contraception deemed reliable by investigator
   6. Subject is female and plans to become pregnant during the course of the study
   7. Subject has had a hypoglycemic seizure within the past 6 months
   8. Subject has had hypoglycemia resulting in loss of consciousness within the past 6 months prior to screening visit
   9. Subject has had an episode of DKA within the past 6 months prior to

screening visit
10. Subject has a history of a seizure disorder
11. Subject has central nervous system or cardiac disorder resulting in syncope
12. Subject has a history of myocardial infarction, unstable angina, coronary artery bypass surgery, coronary artery stenting, transient ischemic attack (TIA), cerebrovascular accident (CVA), angina, congestive heart failure, ventricular rhythm disturbances or thromboembolic disease
13. Subject has a hematocrit (Hct) lower than the normal reference range
14. Subject has a history of adrenal insufficiency

2. Follow-up Schedule

At the end of the study, subjects removed all study devices. Upon removal, all the Sensor insertion sites were examined and evaluated by the study staff. Sensors were visually inspected at the site. Study investigators documented any Adverse Device Effects (including skin irritations) and evaluated safety issues related to system use during the study. No long-term follow up was included in this study protocol.

3. Clinical Endpoints

Because this was an observational study, it did not include traditional analysis of clinical endpoints. The data were presented using multiple analyses as described in the Study Results section below.

Safety of the sensor was determined by skin and insertion site reactions.

B. Accountability of PMA Cohort

Of the 93 subjects that entered the study, 4 subjects failed the screening, and 89 subjects were randomized into one of two groups that determined when they participated in the in-clinic frequent sample testing (day testing or night testing). Of these 89 randomized subjects, 7 subjects did not complete the study for the following reasons:

- One subject withdrew their informed consent
- One subject withdrew due to work schedule
- One subject withdrew due to school schedule
- One subject did not show up for insertion visit
- After review of study dates, one subject withdrew.
- A sensor failed on frequent sampling day 7 and subject did not have adequate time off work to reschedule
- After a sensor fell out due to sweating, before frequent sample day 7, the subject decided to withdraw so they did not have to complete a second round of frequent sample testing.

A total of 82 subjects underwent frequent sample testing and completed the study. Eighty-eight (88) subjects completed the first frequent sample testing on day 1, 87 subjects completed frequent sample testing on day 3, and 79 subjects completed frequent sample

testing on day 7. Three (3) subjects completed the study by attending the last visit, but did not complete frequent sample testing on day 7.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a pivotal CGM accuracy study performed in the US.

Table 2A: Study Population Demographics

Characteristics	**All Subjects N=89**
Age (years)	
N	89
Mean (SD)	41.7 (19.14)
Median	42
Min, Max	15.0, 75.0
Gender, number (%)	
Female not of child bearing potential	16 (18.0%)
Female of child bearing potential	27 (30.3%)
Male	46 (51.7%)
Race, number (%)	
Asian	3 (3.4%)
Black/African American	8 (9.0%)
Native Hawaiian/other Pacific Islander	1 (1.1%)
Other	3 (3.4%)
White	74 (83.1%)
Ethnicity, number (%)	
Hispanic/Latino	3 (3.4%)
Non-Hispanic/Non-Latino	86 (96.6%)
Height (cm)	
N	89
Mean (SD)	171.6 (9.24)
Median	170.4
Min, max	148.5, 198.2
Weight (kg)	
N	89
Mean (SD)	83.3 (24.16)
Median	77
Min, max	45.9, 188.6
Body mass index (kg/m2)	
N	89
Mean (SD)	28.2 (7.14)
Median	26.5
Min, Max	17.9, 53.2

A1C (%)	
N	89
Mean (SD)	7.9 (1.38)
Median	7.8
Min, max	5.3, 12.6

Table 2B: Baseline Parameters

Characteristics	**All Subjects N=89**
Hematocrit (%)	
N	89
Mean (SD)	43.8 (3.61)
Median	43.3
Min, max	35.3, 52.8
Systolic blood pressure (mmHg)	
N	89
Mean (SD)	120.6 (14.41)
Median	120
Min, max	87.0, 164.0
Diastolic blood pressure (mmHg)	
N	89
Mean (SD)	76.8 (8.52)
Median	78
Min, max	57.0, 97.0

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the entire study cohort of 89 subjects. The key safety outcomes for this study are presented below.

Adverse effects that occurred in the PMA clinical study:

The safety of the Guardian Sensor was assessed by evaluation of the incidence of all adverse events, Adverse Device Effects (ADEs), Serious Adverse Device Events (SADEs), and Unanticipated Adverse Device Effects (UADEs) experienced by study subjects. Adverse events (AEs) were listed in terms of severity and relationship to device. Sensor insertion site and adhesive area were examined for erythema, edema and infection. The local skin reactions from the insertion site or the adhesive were also evaluated.

There were five (5) AEs reported during the study. All adverse events were resolved and subjects recovered completely without residual sequelae:

- There was one report of gastroenteritis, thought to be viral infection related.

- There was one report of worsening of benign prostatic hypertrophy, requiring Foley catheter insertion by the subject's urologist.
- There was one report of rash at the IV site, which cleared up by the next day without intervention.
- There was one report of upper respiratory symptoms that resolved.
- There was one report of a skin blister from skin tac used under tape.

There were no reports of subject death.
There were no reports of device-related serious adverse events (SAEs).
There were no reports of DKA.
There were no reports of severe hyperglycemia.
There were no reports of severe hypoglycemia.
There were no reports of non-device-related SAEs.
There were no reports of device-related adverse events.
The incidence of adverse events directly related to the CGM in the intended use population is not expected to differ significantly from the event rate observed during the Sensor accuracy study (G140053) or those observed for other approved CGM devices. Based on (FDA-analyzed) postmarket adverse event reports for similar CGM devices, no additional concerns regarding adverse events were raised for CGMs.

2. Effectiveness Results

The analysis of effectiveness was based on the observed accuracy of the sensor in 82 evaluable patients. The data are presented in Tables 3 to 34 below.

Tables 3 to 6 provide the Guardian sensor values and the percent difference with respect to comparator method (CM) values when the sensor was calibrated every 12 hours and when the sensor was calibrated three to four times per day, for senors inserted in the abdomen and upper arm locations, respectively.

Table 3: CGM Difference to CM within Reference Glucose Range, Calibrating Every 12 hours, Abdominal Insertion Site

CM Glucose Ranges (mg/dL)	Number of Paired CGM-CM Points	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	12090	10.55	7.84
<40*	12	17.03	16.82
40-60*	353	7.96	7.1
61-80*	1445	9.44	7.55
81-180	6505	9.94	7.14
181-300	3277	10	8
301-350	366	9.63	7.48
351-400	117	9.58	7.58
>400	15	10.85	10.83

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: *Sensor glucose readings are within 40-400 mg/dL.*

Table 4: CGM Difference to CM within CM Glucose Ranges, Calibrating three to four times per day, Abdominal Insertion Site

CM Glucose Ranges (mg/dL)	Number of Paired CGM-CM Points	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	11664	9.64	7.08
<40*	11	16.41	15.05
40-60*	324	7.53	6.6
61-80*	1403	8.81	6.75
81-180	6342	9.33	6.62
181-300	3114	8.57	6.98
301-350	341	8.13	6.26
351-400	114	8.56	7.15
>400	15	10.92	10.83

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: *Sensor glucose readings are within 40-400 mg/dL.*

Table 5. CGM Difference to CM within Reference Glucose Range, Calibrating Every 12 hours, Arm Insertion Site.

CM Glucose Ranges (mg/dL)	Number of Paired CGM-CM Points	Mean Absolute Relative Difference (%) (MARD)	Median Absolute Relative Difference (%) (ARD)
Overall	10526	9.09	6.88
<40*	7	17.24	16.05
40-60*	335	6.44	5.4
61-80*	1345	7.76	5.65
81-180	5644	8.64	6.42
181-300	2766	8.58	7
301-350	308	9.09	7.51
351-400	111	8.47	6.92
>400	10	10.71	10.44

** For glucose range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: *Sensor glucose readings are within 40-400 mg/dL.*

Table 6. CGM Difference to CM within CM Glucose Ranges, Calibrating three to four times per day, Arm Insertion Site

CM Glucose Ranges (mg/dL)	Number of Paired CGM-CM Points	Mean Absolute Relative Difference (%)	Median Absolute Relative Difference (%)
Overall	10771	8.68	6.67
<40*	7	17.24	16.05
40-60*	349	6.42	5.45
61-80*	1372	7.44	5.3
81-180	5795	8.35	6.3
181-300	2785	7.95	6.71
301-350	338	8.27	6.88
351-400	115	8.23	6.76
>400	10	11.44	10.44

** For glucose range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
***Note:** Sensor glucose readings are within 40-400 mg/dL.*

Tables 7 to 10 provide the Guardian sensor values and the percent of data points that fell within 15, 20, 30, 40, and >40 mg/dL or percent of a specific glucose CM range when the sensor was calibrated every 12 hours and when the sensor was calibrated three to four times per day, for senors inserted in the abdomen and upper arm locations, respectively.

Table 7: Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated every 12 hours, Abdominal Insertion Site

CGM Glucose Ranges (mg/dL)	Number of CGM-CM	Percent of CM Within 15/15% of CGM	Percent of CM Within 20/20% of CGM	Percent of CM Within 30/30% of CGM	Percent of CM Within 40/40% of CGM	Percent of CM Greater Than 40/40% of CGM
Overall	12090	76.6	85.7	94.3	97.3	2.7
>=40-60*	781	57.7	73.2	90.7	96.9	3.1
>60-80*	1350	76.1	83.4	93.4	96.8	3.2
>80-180	6769	76.5	85.3	93.5	96.5	3.5
>180-300	2833	80.8	90	97.1	98.9	1.1
>300-350	286	86.4	95.1	99.7	100	0
>350-400	71	93	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
***Note:** Sensor glucose readings are within 40-400 mg/dL*

Table 8: Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Abdominal Insertion Site

CGM Glucose Ranges (mg/dL)	Number of CGM-CM	Percent of CM Within 15/15% of CGM	Percent of CM Within 20/20% of CGM	Percent of CM Within 30/30% of CGM	Percent of CM Within 40/40% of CGM	Percent of CM Greater Than 40/40% of CGM
Overall	11664	80.6	88.9	95.9	98.2	1.8
>=40-60*	686	60.2	75.1	92	98.1	1.9
>60-80*	1303	78.7	85.7	93.5	96.7	3.3
>80-180	6549	79.9	88.5	95.7	98	2
>180-300	2782	86.4	93.5	98	99.4	0.6
>300-350	279	92.5	97.8	99.6	100	0
>350-400	65	95.4	100	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
***Note:** Sensor glucose readings are within 40-400 mg/dL*

Table 9: Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated Every 12 hours, Arm Insertion Site

CGM Glucose Ranges (mg/dL)	Number of CGM-CM	Percent of CM Within 15/15% of CGM	Percent of CM Within 20/20% of CGM	Percent of CM Within 30/30% of CGM	Percent of CM Within 40/40% of CGM	Percent of CM Greater Than 40/40% of CGM
Overall	10526	82.5	90.3	96.3	98.7	1.3
>=40-60*	520	77.1	86.9	96	99.6	0.4
>60-80*	1238	88.2	92.5	96.4	99	1
>80-180	5957	80.3	88.5	95.5	98.2	1.8
>180-300	2495	85	93.2	98	99.4	0.6
>300-350	256	90.6	96.9	100	100	0
>350-400	60	90	93.3	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
***Note:** Sensor glucose readings are within 40-400 mg/dL*

Table 10: Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Arm Insertion Site

CGM Glucose Ranges (mg/dL)	Number of CGM-CM	Percent of CM Within 15/15% of CGM	Percent of CM Within 20/20% of CGM	Percent of CM Within 30/30% of CGM	Percent of CM Within 40/40% of CGM	Percent of CM Greater Than 40/40% of CGM
Overall	10771	84.3	91.6	97.3	99.1	0.9
>=40-60*	503	77.1	87.5	96.6	99.6	0.4
>60-80*	1291	89.3	93.4	97.7	99.1	0.9
>80-180	6076	82	90	96.7	98.7	1.3
>180-300	2569	87	94.4	98.3	99.7	0.3
>300-350	271	94.8	98.5	100	100	0
>350-400	61	95.1	96.7	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*
***Note:** Sensor glucose readings are within 40-400 mg/dL*

Tables 11 to 14 provide the number and percentage of CM measurements collected while the continuous glucose monitor read 'low' (< 40 mg/dL), or 'high' (> 400 mg/dL) for sensors calibrated every 12 hours and three to four times per day.

Table 11: The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); Calibrating Every 12 hours, Abdominal and arm insertion sites

CGM Readings	Insertion Site	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Abdomen	Cumulative, n	42	77	139	150	4	154
		Cumulative %	27%	50%	90%	97%	3%	-
	Arm	Cumulative, n	17	35	67	74	1	75
		Cumulative %	23%	47%	89%	99%	1%	-

Table 12: The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating every 12 hours, Abdominal and arm insertion sites

CGM Readings	Insertion Site	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative, %	89%	100%	100%	100%	0%	-
	Arm	Cumulative, n	8	8	9	9	0	9
		Cumulative, %	89%	89%	100%	100%	0%	-

Table 13: The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); calibrating three to four times per day, Abdominal and arm insertion sites

CGM Readings	Insertion Site	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Abdomen	Cumulative, n	33	64	108	119	4	123
		Cumulative, %	27%	52%	88%	97%	3%	-
	Arm	Cumulative, n	18	35	66	72	1	73
		Cumulative, %	25%	48%	90%	99%	1%	-

Table 14: The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating three to four times per day, Abdominal and arm insertion sites

CGM Readings	Insertion Site	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative, %	89%	100%	100%	100%	0%	-
	Arm	Cumulative, n	8	8	8	8	0	8
		Cumulative, %	100%	100%	100%	100%	0%	-

Tables 15 through 18 show the percentage of concurring CGM readings compared to CM values. Tables 21 and 22 show the concurrence of the CGM values compared to CM values when calibrating every 12 hours, and when calibrating every three to four hours, respectively. With ideal performance, the CGM readings would match the CM values. For example, with perfect concurrence, the shaded boxes would be 100 percent.

Table 15: Concurrence of CM Values and CGM Readings Using CM Glucose Ranges; Calibrating Every 12 Hours, Abdominal Insertion Site

CGM Reference Glucose Ranges (mg/dL)	Percent of Matched Pairs in Each CM Glucose Range for Each CGM Glucose Range											
	CM (mg/dL)											
	Number of Paired CGM-CM points	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
A) <40	154	0.0% (0/0)	50.0% (77/154)	47.4% (73/154)	2.6% (4/154)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40-60	781	1.2% (9/781)	30.7% (240/781)	57.2% (447/781)	10.6% (83/781)	0.3% (2/781)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	1350	0.2% (3/1350)	8.3% (112/1350)	60.1% (811/1350)	29.2% (394/1350)	2.1% (28/1350)	0.1% (2/1350)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	2953	0.0% (0/0)	0.0% (1/2953)	6.3% (185/2953)	73.0% (2157/2953)	18.2% (537/2953)	2.0% (60/2953)	0.4% (13/2953)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	2784	0.0% (0/0)	0.0% (0/0)	0.1% (2/2784)	8.8% (245/2784)	67.7% (1885/2784)	20.3% (565/2784)	2.8% (79/2784)	0.3% (8/2784)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1875	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1875)	10.0% (188/1875)	60.2% (1128/1875)	28.2% (529/1875)	1.5% (28/1875)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1382	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (4/1382)	8.0% (111/1382)	61.1% (844/1382)	28.1% (389/1382)	2.3% (32/1382)	0.1% (2/1382)	0.0% (0/0)
H) >250-300	608	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/608)	10.9% (66/608)	61.2% (372/608)	25.5% (155/608)	2.1% (13/608)	0.0% (0/0)
I) >300-350	286	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.0% (3/286)	19.9% (57/286)	55.2% (158/286)	22.4% (64/286)	1.4% (4/286)
J) >350-400	71	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (1/71)	29.6% (21/71)	53.5% (38/71)	15.5% (11/71)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table 16: Concurrence of CM Values and CGM Readings Using CM Glucose Ranges; Calibrating 3 to 4 Times per Day, Abdominal Insertion Site

CGM Reference Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range											
	CM (mg/dL)											
	Number of Paired CGM-CM Points	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
A) <40	123	0.0% (0/0)	52.0% (64/123)	44.7% (55/123)	3.3% (4/123)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40-60	686	1.3% (9/686)	31.6% (217/686)	57.0% (391/686)	9.9% (68/686)	0.1% (1/686)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	1303	0.2% (2/1303)	8.1% (106/1303)	63.4% (826/1303)	26.2% (342/1303)	1.9% (25/1303)	0.2% (2/1303)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	2864	0.0% (0/0)	0.0% (1/2864)	6.5% (186/2864)	74.5% (2133/2864)	17.5% (502/2864)	1.3% (36/2864)	0.2% (6/2864)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	2681	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.0% (241/2681)	69.9% (1874/2681)	19.1% (512/2681)	1.8% (49/2681)	0.2% (5/2681)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1820	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1820)	10.3% (188/1820)	63.6% (1157/1820)	24.9% (454/1820)	1.0% (19/1820)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1314	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (7/1314)	8.5% (112/1314)	65.3% (858/1314)	24.6% (323/1314)	1.1% (14/1314)	0.0% (0/0)	0.0% (0/0)
H) >250-300	652	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/652)	11.3% (74/652)	63.5% (414/652)	22.9% (149/652)	2.0% (13/652)	0.0% (0/0)
I) >300-350	279	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (50/279)	59.5% (166/279)	21.1% (59/279)	1.4% (4/279)
J) >350-400	65	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (12/65)	64.6% (42/65)	16.9% (11/65)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table 17: Concurrence of CM Values and CGM Readings Using CM Glucose Ranges; Calibrating Every 12 Hours, Arm Insertion Site

CGM Reference Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range											
	CM (mg/dL)											
	Number of Paired CGM-CM Points	<40	>=40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
A) <40	75	2.7% (2/75)	44.0% (33/75)	52.0% (39/75)	1.3% (1/75)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40-60	520	1.0% (5/520)	41.9% (218/520)	51.7% (269/520)	5.4% (28/520)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	1238	0.2% (2/1238)	9.2% (114/1238)	70.3% (870/1238)	20.0% (247/1238)	0.4% (5/1238)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	2722	0.0% (0/0)	0.1% (3/2722)	7.5% (203/2722)	74.0% (2014/2722)	17.7% (481/2722)	0.8% (21/2722)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	2348	0.0% (0/0)	0.0% (0/0)	0.1% (3/2348)	9.2% (215/2348)	70.4% (1652/2348)	18.0% (423/2348)	2.3% (54/2348)	0.0% (1/2348)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1614	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1614)	9.4% (151/1614)	64.7% (1044/1614)	24.8% (400/1614)	0.9% (14/1614)	0.2% (3/1614)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1212	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.6% (7/1212)	6.8% (83/1212)	63.9% (774/1212)	27.3% (331/1212)	1.4% (17/1212)	0.0% (0/0)	0.0% (0/0)
H) >250-300	556	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/556)	9.4% (52/556)	65.1% (362/556)	23.9% (133/556)	1.4% (8/556)	0.0% (0/0)
I) >300-350	256	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.0% (46/256)	56.6% (145/256)	24.6% (63/256)	0.8% (2/256)
J) >350-400	60	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.3% (2/60)	16.7% (10/60)	66.7% (40/60)	13.3% (8/60)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	55.6% (5/9)	33.3% (3/9)

Table 18: Concurrence of CM Values and CGM Readings Using CM Glucose Ranges; Calibrating 3 to 4 Times per Day, Arm Insertion Site

CGM Reference Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range											
	CM (mg/dL)											
	Number of Paired CGM-CM Points	**<40**	**>=40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
A) <40	73	2.7% (2/73)	45.2% (33/73)	50.7% (37/73)	1.4% (1/73)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40-60	503	1.0% (5/503)	45.9% (231/503)	48.3% (243/503)	4.8% (24/503)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	1291	0.2% (2/1291)	8.9% (115/1291)	72.3% (933/1291)	18.4% (237/1291)	0.3% (4/1291)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	2756	0.0% (0/0)	0.1% (3/2756)	7.0% (194/2756)	75.9% (2092/2756)	16.5% (456/2756)	0.4% (11/2756)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	2442	0.0% (0/0)	0.0% (0/0)	0.1% (2/2442)	9.3% (228/2442)	71.4% (1743/2442)	18.0% (439/2442)	1.2% (30/2442)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1588	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1588)	9.4% (150/1588)	66.3% (1053/1588)	23.5% (373/1588)	0.6% (9/1588)	0.1% (1/1588)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1246	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (6/1246)	7.4% (92/1246)	65.7% (818/1246)	25.1% (313/1246)	1.4% (17/1246)	0.0% (0/0)	0.0% (0/0)
H) >250-300	613	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/613)	8.6% (53/613)	65.1% (399/613)	24.6% (151/613)	1.5% (9/613)	0.0% (0/0)
I) >300-350	271	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.2% (44/271)	59.8% (162/271)	23.2% (63/271)	0.7% (2/271)
J) >350-400	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.9% (3/61)	11.5% (7/61)	70.5% (43/61)	13.1% (8/61)
K) >400	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	37.5% (3/8)

Tables 19 to 22 show the sensor stability by comparing the CM values collected during frequent sample testing days 1, 3, and 7 to their paired sensor points. The tables stratify the paired CM-sensor data by agreement rates within 15/20/30/40 mg/dL for glucose values ≤ 80 mg/dL, or within 15%/20%/30%/40% for glucose values > 80 15, 20/20, 30/30, 40/40 and >40/40 mg/dL and percent, respectively..

Table 19: Sensor Stability (accuracy over time) for Calibration Every 12 Hours. Abdomen Insertion

Day of Wear	Numbe of Paired CGM-CM Points	Mean absolute percent difference (%)	Median absolute percent difference (%)	Percent within 15/15% CM	Percent within 20/20% CM	Percent within 30/30% CM	Percent within 40/40% CM	Percent greater than 40/40% CM
1	**4294**	13.0	10.2	68.3	81	93.1	97.9	2.1
3	4533	8.9	6.9	86.6	93.8	98.2	99.5	0.5
7	3263	9.5	6.8	81.9	90.1	97	99.2	0.8

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40mg/dL.*

Table 20: Sensor Stability (accuracy over time) for Calibration Every 12 Hours. Arm Insertion

Days of Wear	Number of Paired CGM-CM Points	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent Within 15/15% CM	Percent Within 20/20% CM	Percent Within 30/30% CM	Percent Within 40/40% CM	Percent Greater Than 40/40% CM
1	3390	10.8	8.2	77.4	86.5	96.1	99.6	0.4
3	4243	8.1	6.5	89.0	95.7	99.3	99.7	0.3
7	2893	8.5	6.3	87.3	93.1	97.7	99.6	0.4

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40mg/dL.*

Table 21: Sensor Stability (accuracy over time) for Calibration 3 to 4 Times per Day. Abdomen Insertion

Day of Wear	Number of Paired CGM-CM Points	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within 15/15% CM	Percent Within 20/20% CM	Percent Within 30/30% CM	Percent Within 40/40% CM	Percent Greater Than 40/40% CM
1	4136	11.7	8.8	74.4	85.3	94.6	98.2	1.8
3	4378	8.3	6.3	88.3	94.8	98.6	99.7	0.3
7	3150	8.7	6.2	85.5	92.1	97.7	99.6	0.4

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40mg/dL.*

Table 22: Sensor Stability (accuracy over time) for Calibration 3 to 4 Times per Day. Arm Insertion

Days of Wear	Number of Paired CGM-CM Points	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within 15/15% CM	Percent Within 20/20% CM	Percent Within 30/30% CM	Percent Within 40/40% CM	Percent Greater Than 40/40% CM
1	3591	10.3	7.8	79.3	88.3	97.1	99.6	0.4
3	4198	7.8	6.3	90.6	96.5	99.3	99.7	0.3

Days of Wear	Number of Paired CGM-CM Points	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within 15/15% CM	Percent Within 20/20% CM	Percent Within 30/30% CM	Percent Within 40/40% CM	Percent Greater Than 40/40% CM
7	2982	8.1	6.2	88.8	94.1	98.5	99.8	0.2

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Tables 23 through 26 provide the percent agreement of Guardian Sensor (3) and comparator method (CM) within a specific time range after calibration. These tables provide that the percent agreement within 15, 20, 30, 40, and >40 % mg/dL is highest from zero to two hours after calibration for sensors calibrated every 12 hours and three to four times per day, respectively.

Table 23: Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating every 12 hours. Abdomen Insertion

Time After Calibration	Number of Paired CGM-CM Points	Percentage (%) Agreement				
		± 15% (± 15mg/dL)	± 20% (± 20mg/dL)	± 30% (± 30mg/dL)	± 40% (± 40mg/dL)	> ±40% (± 40mg/dL)
0–2 hours	2999	85	92.6	97.8	99.6	0.4
2–4 hours	2667	75.1	85.9	95.3	98.8	1.2
4–6 hours	2138	71.4	82	92.7	97.6	2.4
6–8 hours	1521	77.6	88.4	97	99.3	0.7
8–10 hours	1523	84.2	91.1	97.6	99.3	0.7
10–12 hours	1242	79.8	89.5	96.3	98.6	1.4

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Table 24: Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating every 12 hours. Arm Insertion

Time After Calibration	Nunber of Paired CGM-CM Points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0–2 hours	2555	87.8	93.2	98.1	99.6	0.4
2–4 hours	2242	84.3	92.6	98.6	99.9	0.1
4–6 hours	1787	80.8	89.1	96.6	99.2	0.8
6–8 hours	1396	84.9	91.5	97.9	99.8	0.2
8–10 hours	1412	86	92.7	97.7	99.7	0.3
10–12 hours	1102	83.6	92.5	97.7	99.5	0.5

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Table 25: Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating three to four times per day. Abdomen Insertion

Time After Calibration	Number of Paired CGM-CM Points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	4585	87	93.5	98.1	99.7	0.3
2-4 hours	3949	80.7	89.9	96.7	99	1
4-6 hours	2856	78.7	87.6	95.5	98.5	1.5
6-8 hours	227	74.9	86.3	96.9	99.6	0.4
8-10 hours	35	82.9	85.7	91.4	94.3	5.7
10-12 hours	12	91.7	91.7	91.7	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Table 26: Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating three to four times per day. Arm Insertion

CM Glucose Ranges (mg/dL)	Number of Paired CGM-CM Points	± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	4156	89.2	94.3	98.5	99.8	0.2
2-4 hours	3640	86.3	93.6	98.8	99.8	0.2
4-6 hours	2684	82.6	90.7	97.4	99.3	0.7
6-8 hours	242	81	91.7	97.5	100	0
8-10 hours	39	76.9	94.9	97.4	100	0
10-12 hours	10	50	70	100	100	0

**For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Tables 27 to 30 provide data to present sensor accuracy over specific glucose rates of change. These concurrence tables provide the percent of matched CM pairs to CGM values over specific glucose rates of change for sensors calibrated every 12 hours for the abdomen (Table 27) and the arm (Table 28) and three to four times per day for the abdomen (Table 29) and for the arm (Table 30).

Table 27: Concurrence of CGM and Comparator Method (CM) Rate of Change Stratified by Different CGM Rate Ranges. Calibration Every 12 hours. Abdomen Insertion

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs in Each CM Rate Range for Each CGM Rate Range							
	CM Rate of Change (mg/dL/min)							
	Number of Paired CGM-CM Points	<-3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	>3
≤ 3	27	25.9% (7/27)	22.2% (6/27)	25.9% (7/27)	22.2% (6/27)	3.7% (1/27)	0.0% (0/0)	0.0% (0/0)
[-3, -2)	135	5.9% (8/135)	30.4% (41/135)	43.0% (58/135)	20.7% (28/135)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
[-2, -1)	1001	0.5% (5/1001)	4.3% (43/1001)	39.9% (399/1001	55.0% (551/1001)	0.3% (3/1001)	0.0% (0/0)	0.0% (0/0)
[-1, 1]	9477	0.2% (16/9477)	0.2% (21/9477)	2.6% (246/9477	92.7% (8781/9477	4.0% (375/9477	0.3% (29/9477)	0.1% (9/9477)
(1, 2]	1059	0.1% (1/1059)	0.0% (0/0)	0.4% (4/1059)	42.4% (449/1059)	48.6% (515/1059	7.6% (80/1059)	0.9% (10/1059)
(2, 3]	308	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.0% (34/308)	46.4% (143/308)	35.4% (109/308)	7.1% (22/308)
> 3	83	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	7.2% (6/83)	20.5% (17/83)	34.9% (29/83)	37.3% (31/83)

Table 28: Concurrence of CGM and Comparator Method (CM) Rate of Change Stratified by Different CGM Rate Ranges. Calibration Every 12 hours. Arm Insertion

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Paired CGM-CM Points	<-3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	>3
<-3	22	31.8% (7/22)	40.9% (9/22)	13.6% (3/22)	13.6% (3/22)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
[-3, -2)	92	5.4% (5/92)	30.4% (28/92)	48.9% (45/92)	15.2% (14/92)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
[-2, -1)	893	0.4% (4/893)	4.5% (40/893)	39.3% (351/893)	55.7% (497/893)	0.1% (1/893)	0.0% (0/0)	0.0% (0/0)
[-1, 1]	8251	0.2% (15/8251)	0.1% (12/8251)	2.8% (229/8251)	92.9% (7664/8251)	3.6% (301/8251)	0.3% (22/8251)	0.1% (8/8251)
1, 2]	936	0.1% (1/936)	0.0% (0/0)	0.2% (2/936)	38.1% (357/936)	54.2% (507/936)	6.7% (63/936)	0.6% (6/936)
(2, 3]	269	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	8.9% (24/269)	44.2% (119/269)	39.8% (107/269)	7.1% (19/269)
>3	63	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.2% (2/63)	9.5% (6/63)	39.7% (25/63)	47.6% (30/63)

Table 29: Concurrence of CGM and Comparator Method (CM) Rate of Change Stratified by Different CGM Rate Ranges. Calibrating 3 to 4 Times per Day. Abdomen Insertion

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Paired CGM-CM Points	<-3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	>3
≤ 3	25	28.0% (7/25)	28.0% (7/25)	24.0% (6/25)	16.0% (4/25)	4.0% (1/25)	0.0% (0/0)	0.0% (0/0)
[−3, −2)	134	6.0% (8/134)	29.8% (40/134)	42.5% (57/134)	20.9% (28/134)	0.7% (1/134)	0.0% (0/0)	0.0% (0/0)
[−2, −1)	967	0.5% (5/967)	4.6% (44/967)	38.7% (374/967)	55.9% (541/967)	0.3% (3/967)	0.0% (0/0)	0.0% (0/0)
[−1, 1]	9140	0.2% (16/9140)	0.2% (20/9140)	2.7% (246/9140	92.6% (8462/9140	4.0% (375/9140	0.3% (26/9140)	0.1% (8/9140)
(1, 2]	1024	0.0% (0/0)	0.0% (0/0)	0.2% (2/1024)	43.8% (448/1024)	47.5% (486/1024	7.5% (77/1024)	1.1% (11/1024)
(2, 3]	302	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.3% (34/302)	47.7% (144/302)	35.1% (106/302)	6.0% (18/302)
> 3	72	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.9% (5/72)	22.2% (16/72)	38.9% (28/72)	31.9% (23/72)

Table 30: Concurrence of CGM and Comparator Method (CM) Rate of Change Stratified by Different CGM Rate Ranges. Calibrating 3 to 4 Times per Day. Arm Insertion

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Paired CGM-CM Points	<-3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	>3
<-3	22	31.8% (7/22)	40.9% (9/22)	13.6% (3/22)	9.1% (2/22)	4.5% (1/22)	0.0% (0/0)	0.0% (0/0)
[−3, −2)	102	4.9% (5/102)	32.4% (33/102)	48.0% (49/102)	14.7% (15/102)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
[−2, −1)	933	0.4% (4/933)	4.2% (39/933)	40.1% (374/933)	55.0% (513/933)	0.2% (2/933)	0.0% (0/0)	0.1% (1/933)
[−1, 1]	8388	0.2% (15/8388)	0.1% (12/8388)	2.6% (220/8388)	93.1% (7811/8388)	3.6% (303/8388)	0.2% (20/8388)	0.1% (7/8388)
(1, 2]	972	0.1% (1/972)	0.0% (0/0)	0.1% (1/972)	39.9% (388/972)	52.3% (508/972)	7.0% (68/972)	0.6% (6/972)
(2, 3]	285	0.4% (1/285)	0.0% (0/0)	0.0% (0/0)	10.5% (30/285)	43.9% (125/285)	37.2% (106/285)	8.1% (23/285)

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Paired CGM-CM Points	<-3	[-3, -2)	[-2, -1)	[-1, 1]	(1, 2]	(2, 3]	>3
>3	69	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.3% (3/69)	13.0% (9/69)	42.0% (29/69)	40.6% (28/69)

Precision Analysis

Precision of the System was evaluated by comparing the results from two separate sensors worn (Abdomen vs. Arm) on the same subject at the same time. A total of 84 subjects provided 28,102 pairs of CGM measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 9.36% with a coefficient of variation (%CV) of 6.5%.

Alert performance

Alert performance was evaluated to obtain 'true alert' and 'false alert' rates, and 'correctly detected' and 'missed alert' rates. The descriptions and tables below describe the alert rate performance of the device within this clinical study:

True alert rates

The true alert rate is the rate at which the blood glucose value confirmed that the continuous glucose monitor alert was triggered correctly. For example:

- True Threshold Hypoglycemic alert rate alerted when the continuous glucose monitor read that the user was below the low threshold and the user's blood glucose was actually below that low threshold (within +/- 15 or 30 minutes of the alert)
- True Threshold Hyperglycemic alert rate alerted when the continuous glucose monitor read that the user was above the high threshold and the user's blood glucose was actually above that high threshold (within +/- 15 or 30 minutes of the alert)
- True Predictive Hypoglycemic alert rate alerted when the continuous glucose monitor predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes following the alert
- True Predictive Hyperglycemic alert rate alerted when the continuous glucose monitor predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15 or 30 minutes following the alert.

Table 31: Glucose TRUE Alert Performance Using Every 12 hours

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**
Glucose True Alert Rate: Low glucose Alerts, Abdomen	**50**	25.0%	25.0%	**50**	15.2%	12.3%	**50**	18.2%	16.2%
	60	53.5%	51.9%	**60**	40.7%	37.1%	**60**	46.2%	43.4%
	70	66.9%	66.9%	**70**	52.7%	47.7%	**70**	58.3%	55.2%
	80	69.3%	69.3%	**80**	57.8%	51.1%	**80**	62.2%	58.2%
	90	75.1%	74.4%	**90**	64.0%	58.5%	**90**	67.9%	64.3%
Glucose True Alert Rate: High glucose Alerts, Abdomen	**300**	81.3%	81.3%	**300**	57.8%	54.0%	**300**	65.4%	62.7%
	250	90.2%	90.2%	**250**	64.0%	60.1%	**250**	72.5%	69.8%
	220	91.9%	91.9%	**220**	68.9%	66.3%	**220**	76.6%	74.8%
	180	93.7%	92.8%	**180**	70.5%	66.9%	**180**	78.0%	75.4%
Glucose True Alert Rate: Low glucose Alerts, Arm	**50**	36.8%	36.8%	**50**	21.9%	16.7%	**50**	26.1%	22.4%
	60	69%	67.8%	**60**	47.5%	45.6%	**60**	55.1%	53.5%
	70	77.4%	75.3%	**70**	57.4%	54.5%	**70**	65.6%	63%
	80	77.5%	76.4%	**80**	59.9%	53%	**80**	66.5%	61.9%
	90	74.9%	74.9%	**90**	69%	63.2%	**90**	71.3%	68%
Glucose True Alert Rate: High glucose Alerts, Arm	**300**	81.9%	80.6%	**300**	51.7%	49.7%	**300**	61.2%	59.3%
	250	91.4%	91.4%	**250**	62%	59.8%	**250**	71.1%	69.6%
	220	92.2%	92.2%	**220**	65.7%	62.2%	**220**	74.5%	72.2%
	180	92.9%	92.9%	**180**	68%	63.2%	**180**	76.5%	73.7%

False Alert Rates

The glucose false alert rate is the rate at which the blood glucose value did not confirm that the continuous glucose monitor alert was triggered correctly. For example:

- False Threshold Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was below the low threshold but the users blood glucose was actually above that low threshold (within ± 15 or 30 minutes of the alert); or
- False Threshold Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was above the high threshold but the user's blood glucose was actually below that high threshold (within ± 15 or 30 minutes of the alert); or
- False Predictive Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes following the alert.
- False Predictive Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes following the alert.

Table 32: Glucose FALSE Alert Performance Calibrating Every 12 hours

	Threshold Only			**Predictive Only**			**Threshold & Predictive**		
	mg/dL	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**
Glucose False Alert Rate: Low Glucose Alerts, Abdomen	**50**	75.0%	75.0%	**50**	84.8%	87.7%	**50**	81.8%	83.8%
	60	46.5%	48.1%	**60**	59.3%	62.9%	**60**	53.8%	56.6%
	70	33.1%	33.1%	**70**	47.3%	52.3%	**70**	41.7%	44.8%
	80	30.7%	30.7%	**80**	42.2%	48.9%	**80**	37.8%	41.8%
	90	24.9%	25.6%	**90**	36.0%	41.5%	**90**	32.1%	35.7%
Glucose False Alert Rate: High Glucose Alerts, Abdomen	**300**	18.8%	18.8%	**300**	42.2%	46.0%	**300**	34.6%	37.3%
	250	9.80%	9.80%	**250**	36.0%	39.9%	**250**	27.5%	30.2%
	220	8.10%	8.10%	**220**	31.1%	33.7%	**220**	23.4%	25.2%
	180	6.30%	7.20%	**180**	29.5%	33.1%	**180**	22.0%	24.6%
Glucose False Alert Rate: Low Glucose Alerts, Arm	**50**	63.2%	63.2%	**50**	84.8%	87.7%	**50**	81.8%	83.8%
	60	31%	32.2%	**60**	59.3%	62.9%	**60**	53.8%	56.6%
	70	22.6%	24.7%	**70**	47.3%	52.3%	**70**	41.7%	44.8%
	80	22.5%	23.6%	**80**	42.2%	48.9%	**80**	37.8%	41.8%
	90	25.1%	25.1%	**90**	36.0%	41.5%	**90**	32.1%	35.7%
Glucose False Alert Rate: High Glucose Alerts, Arm	**300**	18.1%	19.4%	**300**	48.3%	50.3%	**300**	38.8%	40.7%
	250	8.6%	8.6%	**250**	38%	40.2%	**250**	28.9%	30.4%
	220	7.8%	7.8%	**220**	34.3%	37.8%	**220**	25.5%	27.8%
	180	7.1%	7.1%	**180**	32%	36.8%	**180**	23.5%	26.3%

Correct Detection Rates

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts).

Table 33: Glucose Correct Detection Alert Performance Calibrating Every 12 hours

	Threshold Only			**Predictive Only**			**Threshold & Predictive**		
	mg/dL	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**
Glucose Correct Detection Rate: Low Glucose Alerts, Abdomen	**50**	64.0%	64.0%	**50**	76.0%	68.0%	**50**	76.0%	68.0%
	60	83.3%	82.1%	**60**	94.0%	88.1%	**60**	94.0%	89.3%
	70	90.5%	90.5%	**70**	94.2%	89.8%	**70**	94.2%	92.0%
	80	87.2%	87.2%	**80**	93.6%	87.2%	**80**	93.6%	89.9%
	90	91.1%	88.7%	**90**	94.6%	89.5%	**90**	95.7%	92.2%
Glucose Correct Detection Rate: High Glucose Alerts,	**300**	75.3%	75.3%	**300**	95.3%	92.9%	**300**	95.3%	94.1%
	250	81.5%	80.9%	**250**	96.5%	91.3%	**250**	96.5%	93.6%
	220	90.1%	89.2%	**220**	94.8%	93.5%	**220**	95.3%	94.4%
	180	93.1%	91.4%	**180**	96.6%	93.4%	**180**	96.9%	95.4%
Glucose Correct Detection Rate: Low Glucose Alerts, Arm	**50**	66.7%	66.7%	**50**	95.2%	71.4%	**50**	95.2%	76.2%
	60	86.3%	83.6%	**60**	98.6%	94.5%	**60**	98.6%	97.3%
	70	90.2%	88.6%	**70**	92.7%	90.2%	**70**	93.5%	91.9%
	80	89%	88.4%	**80**	94.8%	86.6%	**80**	95.9%	92.4%
	90	91.7%	90.4%	**90**	96.9%	91.7%	**90**	97.8%	95.6%
Glucose Correct Detection Rate: High Glucose Alerts, Arm	**300**	74.4%	71.8%	**300**	93.6%	89.7%	**300**	93.6%	89.7%
	250	80.9%	79.6%	**250**	96.7%	90.8%	**250**	96.7%	91.4%
	220	90.1%	89.2%	**220**	96.1%	93.6%	**220**	96.1%	95.6%
	180	93.2%	92.2%	**180**	98.1%	94.2%	**180**	98.7%	96.4%

Missed Detection Rates

The Missed Detection Rate is the rate that the device did not alert when it should have (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts). For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Table 34: Glucose Missed Detection Alert Performance Calibrating Every 12 hours

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**	**mg/dL**	**30 min**	**15 min**
Glucose Missed Detection Rate: Low Glucose Alerts, Abdomen	**50**	36.0%	36.0%	**50**	24.0%	32.0%	**50**	24.0%	32.0%
	60	16.7%	17.9%	**60**	6.0%	11.9%	**60**	6.0%	10.7%
	70	9.5%	9.5%	**70**	5.8%	10.2%	**70**	5.8%	8.0%
	80	12.8%	12.8%	**80**	6.4%	12.8%	**80**	6.4%	10.1%
	90	8.9%	11.3%	**90**	5.4%	10.5%	**90**	4.3%	7.8%
Glucose Missed Detection Rate: High Glucose Alerts, Abdomen	**300**	24.7%	24.7%	**300**	4.7%	7.1%	**300**	4.7%	5.9%
	250	18.5%	19.1%	**250**	3.5%	8.7%	**250**	3.5%	6.4%
	220	9.9%	10.8%	**220**	5.2%	6.5%	**220**	4.7%	5.6%
	180	6.9%	8.6%	**180**	3.4%	6.6%	**180**	3.1%	4.6%
Glucose Missed Detection Rate: Low Glucose Alerts, Arm	**50**	33.3%	33.3%	**50**	4.8%	28.6%	**50**	4.8%	23.8%
	60	13.7%	16.4%	**60**	1.4%	5.5%	**60**	1.4%	2.7%
	70	9.8%	11.4%	**70**	7.3%	9.8%	**70**	6.5%	8.1%
	80	11%	11.6%	**80**	5.2%	13.4%	**80**	4.1%	7.6%
	90	8.3%	9.6%	**90**	3.1%	8.3%	**90**	2.2%	4.4%
Glucose Missed Detection Rate: High Glucose Alerts, Arm	**300**	25.6%	28.2%	**300**	6.4%	10.3%	**300**	6.4%	10.3%
	250	19.1%	20.4%	**250**	3.3%	9.2%	**250**	3.3%	8.6%
	220	9.9%	10.8%	**220**	3.9%	6.4%	**220**	3.9%	4.4%
	180	6.8%	7.8%	**180**	1.9%	5.8%	**180**	1.3%	3.6%

3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes:

Guardian sensor performance was evaluated withinstudy population subgroups, such as the frequent sampling participation group, age(14-21 years

old, 22 years old and above), body mass index (BMI), baseline HbA1c, prior continuous glucose monitor experience, prior pump experience, and exercise activity (during in-clinic portions of the study).

Although the studies were not powered for analysis of subpopulations, no significant differences in performance were noted based on these subgroup analyses.

4. Pediatric Extrapolation

The sponsor provided clinical data in pediatric subjects aged 14 and up. In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population younger than 14 years old. This device is approved for use in persons aged 14 and older.

E. 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. The pivotal clinical study included 6 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Please see the SSED for P160017 for descriptions of the supplemental clinical information relevant to the MiniMed 670G system.

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

This PMA was not reviewed by an advisory panel because FDA had the experience and breadth of knowledge to evaluate safety and effectiveness.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness of the Guardian sensor component was based on the performance evaluation of the Guardian Sensor compared to the blood glucose values measured by the CM during in-clinic sessions spanning the wear period of the sensor (7 days). The performance data presented above (Tables 3 to 34) established the sensor performance across the claimed measuring range (40 to 400 mg/dL glucose), the precision, and thecalibration frequency (calibrate minimally every 12 hours or 3-4

times a day) of the 7-day wear period for the Guardian sensor in the abdomen and the arm. The performance data presented above also established the performance of the alarms and alerts of the Guardian sensor.

The results of the clinical studies performed to support approval establish a reasonable assurance that the Guardian Sensor (3) is effective for its intended use in the abdomen and the arm.

B. Safety Conclusions

The risks of the device are based on data collected in a clinical study conducted to support PMA approval as described above. The Guardian Sensor (3) has been approved to be use in the abdomen as a part of the MiniMed 670G System. There are no additional risks associated with the use of the Guardian Sensor (3) in the arm.

C. Benefit-Risk Determination

Summary of Benefits:

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described in the SSED for P160017.

The additional arm insertion site is beneficial to patients, given that the the MiniMed 670G System is intended for chronic use, and the Guardian Sensor (3) should be replaced every 7 days. The additional arm insertion site provides patients with an additional option for sensor insertion site, which is beneficial as sensor and insulin pump insertion sites (often in the abdomen) should be rotated. The performance of the sensor (described in Section X.d, Safety and Effectiveness Results, above) at the arm insertion site is at least comparable to the performance of the sensor at the abdomen insertion site.

The benefits of the MiniMed 670G System otherwise remain unchanged from P160017.

Summary of Risks:

The additional arm insertion site is not expected to pose additional risks that translate to harm to patients, given that the performance of the sensor (described in Section X.d, Safety and Effectiveness Results, above) at the arm insertion site is at least comparable to the performance of the sensor at the abdomen insertion site.

The predictive and combined (predictive and threshold) alert performance at the arm insertion site for high sensor glucose values (180 mg/dL, 220 mg/dL, 250 mg /dL and 300 mg/dL) at both +/-15 minutes and +/-30 minutes is reported to be slightly inferior to the reported alert performance for the respective alerts at the abdomen insertion site. Lower true alert rates, higher false alert rates, lower correct detection, and higher missed detection rates are reported for the arm insertion site compared to the abdomen insertion site. Given the relatively small magnitude of the reported

difference in alert performance, as well as the nature of the alert ("hyper" and "predictive component" intrinsically carry less clinical risk than a "hypo" alert), and the comparability of other measures of sensor performance (including % agreement with YSI, concurrence between CGM and YSI at various glucose ranges), there do not appear to be additional questions of safety or effectiveness that arise as a result of this discrepancy in alert performance. However, there is an increased risk of "alert fatigue," that could result in potential inconvenience to the user, but should not translate into an risk of harm to the patient.

The possible need for assistance with sensor insertion specific to the arm insertion site, is sufficiently conveyed through labelling.

The risks of the MiniMed 670G System otherwise remain unchanged from those described in the SSED for P160017.

Summary of Other Factors

Additional factors to be considered in determining probable risks and benefits for the MiniMed 670G System included sensor precision. Although sensor precision between the two arm insertion sites was not obtained during the pivotal study, the sponsor has provided information that supports the precision is comparable between arm versus arm insertion site compared to abdomen versus abdomen insertion site.

Patient Perspectives
Patient perspectives considered during the review included information provided directly to the Agency by patients in written statements and also obtained through discussion with patients at public forums regarding their experience with continuous glucose monitoring system devices in general.

In conclusion, given the available information above, the data support that for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons fourteen years of age and older requiring insulin, as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin, the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The benefits of using the Guardian Sensor (3), inserted in the abdomen or the arm, with the MiniMed 670G System, as discussed above, outweigh the risks.

XIV. CDRH DECISION

CDRH issued an approval order on February 13, 2018.

The applicant's manufacturing facilities have been 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.