SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Continuous Glucose Monitoring System
Device Trade Name:	Dexcom G4 PLATINUM Continuous Glucose Monitoring System
Device Procode:	MDS
Applicant's Name and Address:	Dexcom, Inc. 6340 Sequence Drive San Diego, CA 92121
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P120005/S018
Date of FDA Notice of Approval:	October 21, 2014
Priority Review:	*Not applicable*

The original PMA (P120005) was approved on October 5, 2012. The indications for use are as follows:

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM System results should be based on the trends and patterns seen with several sequential readings over time.

The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to update the algorithm that converts sensor electrical signal to glucose values for the purpose of improving accuracy.

II. INDICATIONS FOR USE

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM System results should be based on the trends and patterns seen with several sequential readings over time.

III. CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The Dexcom G4 PLATINUM System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.

- Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Dexcom G4 PLATINUM Continuous Glucose Monitoring System labeling.

V. DEVICE DESCRIPTION

The current supplement is for the modification of the algorithm to the previously approved Dexcom G4 PLATINUM Continuous Glucose Monitoring System. The algorithm modification is referred to as Software 505. The algorithm converts sensor electrical signal to glucose values.

The Dexcom G4 Platinum Continuous Glucose Monitoring System consists of the following components: the G4 Platinum Sensor, the G4 Platinum Transmitter, and the G4 Platinum Receiver.

No modifications were made to the sensor or transmitter in this supplement. The receiver hardware has not changed. The algorithm modifications require new firmware in the receiver.

See the SSED for P120005 for a detailed device description.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the control of diabetes. Control of diabetes can be achieved through a combination of methods and behaviors. Self-behaviors include healthy eating, taking medications, as appropriate, and being active. Methods of controlling glucose levels (glycemic control) have been shown to reduce severe diabetes-related complications. Methods of monitoring glycemic control include periodic measurement of Hemoglobin A1c (HbA1c), which reflects average blood glucose levels over a three month period. Self-monitoring of blood glucose using glucose meters and test strips provides quantitative measurements of fingerstick blood glucose at a single point in time for patients and their healthcare providers to monitor the effectiveness of glycemic control and make more immediate treatment modifications.

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

The G4 Platinum System with Software 505 has not been marketed in the United States or any foreign country.

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.

The following are possible effects of inserting a Sensor and wearing the adhesive patch: redness at the sensor insertion site, skin irritation (erythema/edema), local infection, inflammation, pain or discomfort, bleeding at the glucose Sensor insertion site, bruising, itching, scarring or skin discoloration, hematoma, tape irritation, Sensor or needle fracture during insertion, wear or removal.

The risk related to either an inaccurate sensor value which should be outside of the patient's target range, missed alerts, false alerts, false negative hypoglycemia and hyperglycemic readings and false positive hypoglycemia and hyperglycemia is the risk of the device not alerting the user that additional blood glucose testing with a meter should be performed, or of performing unnecessary fingersticks. Patients may rely on the CGM to alert them to low or high glucose levels rather than using blood glucose values from a meter. There is also a risk that patients that are relying on CGM values won't perform

fingerstick testing as often as they would without the CGM. In both cases, blood glucose values may differ from sensor glucose readings.

Inaccurate calculation of the rate of change of glucose by the CGM could prevent a patient from performing additional blood glucose tests or taking measures to stop a trend of increasing or decreasing glucose levels which could lead to serious hypoglycemia or hyperglycemia if no action is taken to stop these glucose trends.

For the specific adverse events that occurred in the clinical studies, please see Section X below and the SSED for the original PMA (P120005).

IX. SUMMARY OF PRECLINICAL STUDIES

The changes from the approved G4 Platinum Continuous Glucose Monitoring System (P120005) are limited to an update in the algorithm (Software 505) in the receiver. The preclinical studies included applicable software verification and validation testing. A summary of the testing performed is summarized below.

Please see the original P120005 SSED for details on other preclinical studies performed that are still applicable to this modified device.

A. Laboratory Studies

Testing was performed to support the algorithm changes in the receiver firmware. The verification and validation activities were completed according to the FDA guidance entitled General Principles of Software Validation: Final Guidance for Industry and FDA Staff released January 11, 2002.

Verification of the software implementation was accomplished through software code reviews, unit testing, and integration testing. These evaluations verify that the software implementation satisfies the design implementation as defined in the Software Requirements Specifications.

Validation of the software implementation is completed and confirmed by examination and provision of objective evidence that the software end products conform to user needs and intended uses, and that the software requirements are consistently fulfilled.

Specific test methods, acceptance criteria, and test results include proprietary information.

B. Animal Studies

No animal studies were conducted using the Dexcom G4 Platinum CGM System.

C. Additional Studies

None

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness with the Dexcom G4 Platinum System for detecting trends and tracking patterns when used as an adjunct to blood glucose testing in subjects with diabetes mellitus. This study (Original Study) was performed in the US under IDE #G110107/S001. Data from this clinical study supported the PMA (P120005) approval decision. Please see the original P120005 SSED for details on this clinical study.

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the *Dexcom G4 Platinum System with Software 505* (Software 505 Study) for detecting trends and tracking patterns when used as an adjunct to blood glucose testing in subjects with diabetes mellitus in the US under IDE #G130238. Data from this clinical study support this PMA supplement approval decision. A summary of the Software 505 study is presented below.

A. Study Design

Patients participated between December 8, 2013 and January 30, 2014. The database for this PMA supplement reflected data collected through January 30, 2014 and included 51 patients. There were 3 investigational sites.

The study was an open-label, prospective, non-randomized, multi-center, single-arm, pivotal clinical study. The purpose of this pivotal study was to evaluate the effectiveness and safety of the G4 CGM with a modified algorithm (Software 505) when used as an adjunctive device to blood glucose testing over a 7-day period in subjects ≥18 years old with diabetes mellitus.

All subjects participated in one sensor session that lasted up to 7 days. For the duration of this study, subjects were instructed to use CGM System information as an adjunct to (and not as a replacement for) standard self-monitored blood glucose (SMBG) guidance of diabetes self-management.

Fifty-four (54) sensors were applied, 3 (6%) of which were replacements. Fifty-two (52) transmitters were used, 1 (2%) of which was a replacement. Fifty-three (53) receivers were used, 2(4%) of which were replacements.

In-Clinic Portion of Study

To collect accuracy information against a laboratory reference assay (Yellow Springs Instrument 2300 STAT Plus Glucose Analyzer (YSI)) and against Self-Monitored Blood Glucose (SMBG), subjects participated in a total of no more than 12 hours of blood draws through an intravenous catheter over one clinic session. During the clinic session, subjects had venous blood draws approximately once every 15 +/- 5 minutes to allow for evaluation of the reference plasma glucose measurements from freshly

collected venous whole blood samples as well as 2 fingersticks per hour for SMBG testing (and as indicated for diabetes management or clinical safety purposes). During the in-clinic session, carbohydrate consumption, insulin dosing, and meal timing were manipulated to obtain a wide range of glucose values (after subjects arrived and completed their calibration requirements, as needed) under close direction and observation of the study investigator staff following protocol specific guidelines. All CGM Systems were blinded (display turned off) to the study staff and subjects for the duration of each in-clinic session.

At-Home Portion of Study

During home use, the CGM was set to unblinded mode. Subjects were asked to use the blood glucose meter and test strips provided to them to take a minimum of 7 SMBG measurements per day (for calibration, diabetes management, and confirming high and low CGM glucose alerts). Subjects were advised to conduct daily activities as normal during the use of the System.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the study was limited to patients who met the following inclusion criteria.

   a. Age 18 or older
   b. Diagnosis of Type 1 diabetes or Type 2 diabetes on Intensive Insulin Therapy (IIT) with known dosing parameters
   c. Would avoid injecting insulin or wearing an insulin pump infusion set within 3 inches of the sensor site
   d. Would participate in one clinic session of up to fifteen (15) hours in duration, during which up to five (minimum of two) deep fingersticks (FS) for arterialization assessment, frequent venous sampling and SMBG testing will be performed with deliberate insulin and glucose challenges
   e. Would take a minimum of seven (7) SMBG measurements per day during home use (as required for System calibration and confirmatory/comparative purposes) with the study-assigned blood glucose meter
   f. Able to refrain from the use of acetaminophen during the sensor wear period
   g. Able to speak, read, and write English

   Patients were not permitted to enroll in the study if they met any of the following exclusion criteria.

   a. Had used acetaminophen for 24-hours prior to sensor insertion and for the 7-days of sensor wear
   b. Had presence of extensive skin changes/diseases at sensor wear site that preclude wearing the sensor on normal skin (e.g. extensive psoriasis, recent burns or severe sunburn, extensive eczema, extensive scarring, extensive tattoos, dermatitis herpetiformis)
   c. Had known allergy to medical-grade adhesives
   d. Were pregnant
   e. Hematocrit (HCT) < 35% for females or < 38% for males

f. Participated in another investigational study protocol (if a subject has recently completed participation in another drug study, the subject must have completed that study at least 30 days prior to being enrolled in this study). Note: current enrollment in another observational study, whereby the subject is in the follow-up phase and no tests/procedures are required, was not exclusionary
g. Were on dialysis or had history of cardiovascular disease (including, but not limited to, ischemic heart disease, peripheral vascular disease, cardiomyopathy, cerebrovascular disease, congenital heart disease, or significant arrhythmias), epilepsy, severe migraines in the past 6 months, adrenal disease, syncope, significant hypoglycemia unawareness, or a history of severe hypoglycemia (requiring emergency medical intervention) within the last 6 months
h. Required a Magnetic Resonance Imaging (MRI) scan, Computed Tomography (CT) scan, or diathermy during the sensor wear period
i. Had any condition that, in the opinion of the Investigator, would interfere with their participation in the study or pose an excessive risk to study staff (e.g. known history of hepatitis B or C)

2. Follow-up Schedule

At the end of the Sensor wear period (7 days), subjects removed the System according to User's Guide instructions and/or training materials provided. Upon removal, all the Sensor insertion and adhesive locations were examined and evaluated by the study staff. Sensor wires were visually inspected at the site for gross mechanical failure per protocol and all inspection observations were documented. Study investigator staff documented any Adverse Device Effects (including 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

Safety data for the System was collected and characterized by device-related Adverse Events (AEs) experienced by study subjects. All skin irritation, any discomfort or pain due to the System wear was also reported as adverse event effects.

The primary effectiveness measurement for this study was the glucose measurement from the System compared to the blood glucose values measured by the reference analyzer during the clinic session.

B. Accountability of PMA Cohort

Fifty-one (51) subjects were enrolled at three (3) clinical sites. 50 subjects participated in the clinic session over the 7-day sensor wear period. One (1) subject did not participate in the clinic session due to illness that was not related to the device. All subjects (51) completed home use requirement of the study.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a continuous glucose monitoring system study performed in the US. See the following tables (Tables 1 and 2) for a description of the demographics and baseline characteristics of the study population.

Table 1. Subject Demographics

Category	Number of Subjects Enrolled (N=51)
Gender, N (%)	
Male	27 (53%)
Female	24 (47%)
Age (years)	
Mean	46.7
SD	15.8
Range	19.7 – 85.5
Race	
White	48 (94%)
American Indian or Alaska Native	1 (2%)
Native Hawaiian or Pacific Islander	1 (2%)
Other	1 (2%)
Ethnicity	
Not Hispanic or Latino	48 (94%)
Hispanic or Latino	3 (6%)

Table 2. Subject Baseline Parameters

Type of Diabetes at Diagnosis	
Type I	44 (86%)
Type II	7 (14%)
Diabetes Duration (years)	
Mean	24.8
SD	14.5
Range	6 – 78
Body Mass Index (kg/m^2)	
Mean	27.4
SD	4.6
Range	20.1 – 39.0
Baseline A1c (%)	
Mean	7.8
SD	1.1
Range	5.8 – 10.9

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on all subjects enrolled for whom at least one sensor was inserted for the purposes of the study. The key safety outcomes and adverse effects are reported below.

All fifty-one (51) subjects were included in the safety analysis. There were no unanticipated adverse device effects (UADEs) or serious adverse events reported.

Adverse effects that occurred in the PMA clinical study:

A total of thirteen (13) adverse events (AEs) were reported during the study. All adverse events were resolved or stable at study termination.

One (1) adverse event (AE) was reported as a study procedure-related AE (left elbow skin blister during clinic session). This AE was deemed of moderate intensity and possibly related to the study; it was on-going but stable at study termination.

Twelve (12) AEs were deemed related to the device due to Sensor insertion and adhesive area irritations. Upon quantitative assessments (Draize's scales) of sensor insertion and adhesive area reactions, 3 (6%) Very Slight (score=1) Erythemas were identified at needle insertion areas; 9 (17%) Very Slight (score=1) Erythemas were identified around adhesive areas. No infections occurred at either insertion or adhesive areas.

Per protocol, the mechanical integrity of each sensor was independently assessed after removal of the sensor from the subcutaneous adipose tissue. There were no reports of broken sensor wires; none of the sensor wires were detached from the sensor pod after the removal.

It should be noted that the safety of the Dexcom G4 Platinum System was not based on this sample alone, but rather on all the available data for the device to date. The safety data from this study were for confirmatory purposes.

2. Effectiveness Results

The analysis of effectiveness was based on the 2263 CGM-reference matched pairs collected within the measurement range (for CGM reading only) of 40-400 mg/dL at study completion. The primary efficacy population consisted of 50 subjects for whom at least one paired CGM-reference value was collected during the clinic session. Key effectiveness outcomes are presented in Tables 3 - 14.

Agreement of CGM System Results with Reference Readings

Agreement of the Dexcom G4 PLATINUM System with Software 505 to reference blood glucose levels was assessed. The percentages of total values

within 15 mg/dL or 15%, within 20 mg/dL or 20%, within 30 mg/dL or 30%, and within 40 mg/dL or 40% of the reference value were calculated. The data were further broken down by glucose concentration range. Table 3-A is categorized within CGM glucose concentrations (first column) and outlines how often a reading on the CGM matched the reference blood glucose reading for the Software 505 Study. Table 3-B similarly describes the data from the Original Study (P120005) for comparison.

Table 3-A: System Agreement to Reference within CGM Glucose Ranges (Software 505 Study)

CGM Glucose Range mg/dL	Number of paired CGM-reference	Percent within 15/15% reference	Percent within 20/20% reference	Percent within 30/30% reference	Percent within 40/40% reference	Percent Greater than 40/40% reference
Overall	2263	86%	93%	98%	99%	1%
40-60	120	89%	94%	98%	100%	0%
61-80	226	91%	96%	99%	100%	0%
81-180	738	84%	92%	98%	99%	1%
181-300	798	86%	93%	98%	99%	1%
301-350	229	86%	94%	98%	99%	1%
351-400	152	80%	92%	97%	100%	0%

Table 3-B: System Agreement to Reference within CGM Glucose Ranges (Original Study)

CGM Glucose Range mg/dL	Number of paired CGM-reference	Percent within 15/15% reference	Percent within 20/20% reference	Percent within 30/30% reference	Percent within 40/40% reference	Percent Greater than 40/40% reference
Overall	9152	71%	82%	92%	97%	3%
40-60	512	67%	78%	88%	94%	6%
61-80	781	73%	85%	94%	98%	2%
81-180	3853	67%	78%	91%	97%	3%
181-300	2784	72%	84%	93%	96%	4%
301-350	775	82%	91%	97%	98%	2%
351-400	447	74%	84%	91%	95%	5%

Agreement of CGM to Reference When CGM Reads "Low" or "High"

The System reports glucose readings between 40 and 400 mg/dL. When the System determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Receiver Status Box. When the System determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver Status Box. Since the System does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the reference

analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Table 4. The table includes the numbers and the cumulative percentages when reference values were less than certain glucose levels (for "LOW"), and when reference values were greater than certain glucose levels (for "HIGH").

Table 4-A. Number and Percentage of Reference (Ref) values when CGM readings are 'LOW' or 'HIGH' (Software 505 Study).

Reference mg/dL							
CGM Readings	CGM-Ref pairs	<55	<60	<70	<80	>80	Total
'LOW'	n	11	16	17	18	0	18
	%	61%	89%	94%	100%	0%	
Reference mg/dL							
CGM Readings	CGM-Ref pairs	>340	>320	>280	>240	<240	Total
'HIGH'	n	40	43	45	45	0	45
	%	89%	96%	100%	100%	0%	

Table 4-B. Number and Percentage of Reference (Ref) values when CGM readings are 'LOW' or 'HIGH' (Original Study).

Reference mg/dL							
CGM Readings	CGM-Ref pairs	<55	<60	<70	<80	>80	Total
'LOW'	n	66	84	123	142	13	155
	%	41%	53%	79%	92%	8%	
Reference mg/dL							
CGM Readings	CGM-Ref pairs	>340	>320	>280	>240	<240	Total
'HIGH'	n	189	220	238	246	2	248
	%	76%	89%	96%	99%	1%	

Table 4-A shows that, per the reference reading, when the System displayed "LOW" (18 occasions), 100% (18 out of 18) of the reference values were less than 80 mg/dL, and 94% (17 out of 18) of the reference values were less than 70 mg/dL. When the System displayed "HIGH" (45 occasions), 100% (45 out of 45) of the reference values were greater than 280 mg/dL. For comparison, in the Original Study the subjects had blood glucose values <80 mg/dL 92% of the time (142 out of 155 occasions) when the CGM read "LOW" and blood glucose values >240 mg/dL 99% of the time when the CGM read "HIGH" (246 out of 248 occasions) (Table 4-B).

Concurrence of System and Laboratory Reference Values

The percentage of concurring CGM readings and reference values were included in Table 5-A (Software 505 Study) and 5-B (Original Study). The tables are

categorized by each CGM glucose range (first column) and describe, for each range of CGM glucose readings, what percentage of paired reference values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings.

Table 5-A. Concurrence of CGM System Readings and Reference values (Software 505 Study).

CGM mg/dL (mmol/L)	Number of Paired CGM-Ref	Percent of matched pairs in each Ref glucose range for each Sensor glucose range Ref mg/dL (mmol/L)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351- 400	>400
<40	18	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%
40- 60	120	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%
61- 80	226	0%	19%	68%	13%	4%	0%	0%	0%	0%	0%	0%
81- 120	347	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%
121- 160	246	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%
161- 200	286	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%
201- 250	376	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%
251- 300	281	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%
301- 350	229	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%
351- 400	152	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%
>400	45	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%

Table 5-B. Concurrence of CGM System Readings and Reference values (Original Study).

CGM mg/dL (mmol/L)	Number of Paired CGM-Ref	Percent of matched pairs in each Ref glucose range for each Sensor glucose range Ref mg/dL (mmol/L)										
		<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351- 400	>400
<40	155	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%
40- 60	512	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%
61- 80	781	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%
81- 120	1706	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%
121- 160	1492	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%
161- 200	1240	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%
201- 250	1181	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%
251- 300	1018	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%
301- 350	775	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%
351- 400	447	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%
>400	248	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%

Evaluation of Accuracy

Accuracy between matched pairs was estimated by calculating the percent difference between the System reading and the reference value. The System and reference values were compared by pairing the System reading that fell immediately after the reference value was collected.

The mean percent difference is the average of all positive and negative percent differences between the two devices and demonstrates whether the System reads higher or lower on average than the reference at each glucose range.

Another analysis is the absolute percent difference. The absolute percent difference provides the percent difference or "distance" between the System and reference values, but does not demonstrate whether the System is reading, on average, higher or lower than the reference standard. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between System readings and reference values.

These accuracy measures in differences are based on 2263 paired glucose results for the Software 505 Study and 9152 paired glucose results for the Original Study. The results are summarized in the following tables (Tables 6-A and 6-B).

Table 6-A. System Difference to Reference within CGM Glucose Ranges (Software 505 Study).

CGM Glucose Ranges mg/dL	# of Paired System -Ref	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	2263	2.5	2.4	9.0	7.0
40-60	120	-3.3	-2.1	6.9	4.8
61-80	226	0.8	1.4	6.7	5.4
81-180	738	3.9	4.1	9.6	8.2
181-300	798	0.6	0.4	8.0	6.1
301-350	229	4.1	3.4	8.0	5.8
351-400	152	7.2	6.3	9.2	7.2

* For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).
Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Table 6-B. System Difference to Reference within CGM Glucose Ranges (Original Study).

CGM Glucose Ranges mg/dL	# of Paired System -Ref	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	9152	2.9	1.7	13.3	9.8
40-60	512	-10.0	-8.2	13.5	9.7
61-80	781	-2.4	-0.4	11.4	8.6
81-180	3853	4.8	3.0	13.8	9.8
181-300	2784	2.1	0.0	11.9	9.2
301-350 (16.7-19.4)	775	3.8	2.8	9.8	7.9

351-400	447	10.4	7.7	12.8	9.1

* For CGM≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).
Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Low and High Glucose Alerts

The System has programmable High and Low Glucose Alerts that can be changed by the user and a non-changeable Low Glucose Alarm set at 55 mg/dL. The labeling instructs the user to consult with their doctor to determine what alert settings would be best for them.

To assess the ability of the System to detect high and low glucose levels the CGM results were compared to reference results at low and high blood glucose levels and it was determined if the alert may have sounded.

Low Glucose Alert: Estimates of how well the adjustable Low Glucose Alert performed are presented below in Tables 7-A and 7-B followed by the definitions of the terms used in the tables. Table 7-A represents the alert evaluation within 15 minutes of the reference reading for the Software 505 Study. Table 7-B represents the alert evaluation within 15 minutes of the reference reading for the Original Study.

Table 7-A. Hypoglycemic Alert and Detection Rate Evaluation Compared to Reference (Software 505 Study).

Alert Level mg/dL	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	71%	29%	68%	32%
60	85%	15%	83%	17%
70	92%	8%	91%	9%
80	95%	5%	90%	10%
90	96%	4%	94%	6%

Table 7-B. Hypoglycemic Alert and Detection Rate Evaluation Compared to Reference (Original Study).

Alert Level mg/dL	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	50%	50%	71%	29%
60	64%	36%	75%	25%
70	79%	21%	83%	17%
80	87%	13%	86%	14%
90	90%	10%	89%	11%

Hypoglycemia Alert Rate:

The Alert Rate shows how often the alert was right or wrong. The True Alert Rate is the % of time the device alarmed when the reference blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the reference blood glucose level was above the alert setting within 15 minutes before or after the device alarmed.

Hypoglycemia Detection Rate:
The Detection Rate shows how often the device recognized and alerted that there was an episode of hypoglycemia or how often it missed such an event. The Hypoglycemia Detection Rate is the % of time the reference blood glucose level was at or below the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the reference blood glucose was at or below the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or below the alert setting.

The above analyses demonstrate the alert performance of the System. For example, in the Software 505 Study, when the Low Glucose Alert was set to 55 mg/dL the alert sounded 71% of the time (i.e., the CGM detected 71% of glucose excursions below 55 mg/dL). In comparison, when the alert was set at 55 mg/dL in the Original Study (Table 7-B) the alert sounded 50% of the time.

High Glucose Alert
Estimates of how well the adjustable High Glucose Alert performed are presented in Tables 8-A and 8-B followed by the definitions of the terms used in the tables:

Table 8-A. Hyperglycemic Alert and Detection Rate Evaluation Compared to Reference (Software 505 Study).

Alert Setting mg/dL	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	98%	2%	100%	0%
140	97%	3%	99%	1%
180	97%	3%	99%	1%
200	96%	4%	98%	2%
220	94%	6%	98%	2%
240	93%	7%	95%	5%
300	86%	14%	90%	10%

Table 8-B. Hyperglycemic Alert and Detection Rate Evaluation Compared to Reference (Original Study).

Alert Setting mg/dL	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	95%	5%	98%	2%

Alert Setting mg/dL	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
140	94%	6%	97%	3%
180	92%	8%	97%	3%
200	92%	8%	97%	3%
220	91%	9%	95%	5%
240	91%	9%	94%	6%
300	82%	18%	86%	14%

Hyperglycemia Alert Rate:
The Alert Rate shows how often the alert was right or wrong. The True Alert Rate is the % of time the device alarmed when the reference blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the reference blood glucose level was below the alert setting within 15 minutes before or after the device alarmed.

Hyperglycemia Detection Rate:
The Detection Rate shows how often the device recognized and alerted that there was an episode of hyperglycemia or how often it missed such an event. The Hyperglycemia Detection Rate is the % of time the reference blood glucose level was at or above the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the reference blood glucose was at or above the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or above the alert setting.

The above analyses demonstrate the High Glucose Alert performance of the System. When the High Glucose Alert was set to 300 mg/dL the alert sounded 86% of the time in the Software 505 Study and 82% of the time in the Original Study.

Calibration Stability
The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, Sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of System readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the reference values in Tables 9-A and 9-B.

Table 9-A. Percentage of System Readings within Reference Values with Data Stratified in 2-hour Increments after Calibration (Software 505 Study).

Time from Calibration	Number of Paired System-Ref	Percent within 15/15%	Percent within 20/20%	Percent within 30/30%	Percent within 40/40%	Percent greater Than 40/40%
0-2 hours	469	93%	97%	99%	100%	0%
2-4 hours	389	90%	97%	99%	100%	0%
4-6 hours	383	85%	91%	97%	98%	2%
6-8 hours	380	79%	90%	97%	98%	2%
8-10 hours	347	83%	92%	98%	100%	0%
10-12 hours	295	80%	90%	98%	100%	0%
12-14 hours	0	--	--	--	--	--

Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Table 9-B. Percentage of System Readings within Reference Values with Data Stratified in 2-hour Increments after Calibration (Original Study).

Time from Calibration	Number of Paired System-Ref	Percent within 15/15%	Percent within 20/20%	Percent within 30/30%	Percent within 40/40%	Percent greater Than 40/40%
0-2 hours	1929	78%	88%	96%	98%	2%
2-4 hours	1516	69%	81%	91%	96%	4%
4-6 hours	1547	69%	79%	91%	95%	5%
6-8 hours	1520	68%	79%	92%	97%	3%
8-10 hours	1555	71%	82%	92%	96%	4%
10-12 hours	1068	65%	77%	91%	96%	4%
12-14 hours	17	65%	76%	82%	88%	12%

Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Sensor Stability and Sensor Life

Sensor Stability

Sensors can be worn for up to 7 days. To assess the stability of sensor performance over the 7 day time period, the sensors in the Software 505 Study were evaluated across the 7-day wear period by comparing CGM performance to reference values on Day 1, Day 4, and Day 7 (Tables 10-A and 10-B). 72 subjects were evaluated in the Original Study across the 7-day wear period while 50 subjects were evaluated in the Software 505 Study across the 7-day wear period (1 subject did not provide in-clinic data due to illness unrelated to the study and was therefore excluded from the sensor stability study).

Sensor Life

Sensors can be worn for up to 7 days. To estimate how reliably a sensor will work over 7 days, 51 sensors were evaluated during the Software 505 Study to

determine how many days of readings each sensor provided. Ninety-eight percent (98%) of the sensors lasted until Day 7. There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

In the Original Study, 108 sensors were evaluated to determine how many days of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7. There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

Table 10-A. System Sensor Stability Relative to Reference (Accuracy over Time, Software 505 Study).

Day of Wear	Number of Paired System-Ref	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 15/15% Ref	Percent within 20/20% Ref	Percent within 30/30% Ref	Percent within 40/40% Ref	Percent greater than 40/40% Ref
Day 1	680	10.7%	7.9%	77%	84%	96%	98%	2%
Day 4	777	8.0%	6.4%	89%	96%	99%	100%	0%
Day 7	806	8.5%	7.2%	90%	97%	99%	100%	0%

Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Table 10-B. System Sensor Stability Relative to Reference (Accuracy over Time, Original Study).

Day of Wear	Number of Paired System-Ref	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 15/15% Ref	Percent within 20/20% Ref	Percent within 30/30% Ref	Percent within 40/40% Ref	Percent greater than 40/40% Ref
Day 1	3023	16.7%	13.2%	59%	71%	86%	94%	6%
Day 4	3108	11.4%	8.2%	77%	87%	95%	98%	2%
Day 7	3021	11.9%	8.9%	76%	87%	95%	98%	2%

Note: CGM readings are within 40 to 400 mg/dL, inclusive.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes (up to 288 readings per day). For a variety of reasons (e.g., sensor failure), the System may not display a glucose reading and readings are "skipped." The number of actual Sensor values provided to subjects over the entire 7-day period and the corresponding percentage is summarized below in Table 11. Adjusted within each system wear-day, the System provided an average of 98% of all expected glucose readings as seen in Table 12.

Table 11. Number of Readings Provided by Each Sensor over 7-Days (Software 505 Study).

% of Total Possible Readings Provided	Total Readings Provided (Min-Max)	% of Systems Providing that Number of Readings
0-25%	0	0%
26-50%	856-856	2%
51-75%	1253-1253	2%
76-100%	1497-1992	96%

Table 12. System Readings within Wear Days (Software 505 Study).

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days (N=51)
Mean	98%	99%	98%	98%	96%	99%	97%	98%
Median	99%	100%	100%	100%	100%	100%	100%	100%
STD	3%	2%	8%	11%	15%	2%	13%	9%

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results. The Bayer Contour Next USB blood glucose meter was used in this study. The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the System in their daily diabetes management when comparing the System readings to their home blood glucose meter results.

Table 13 is categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated. For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the CGM readings to be within 20% of the SMBG values 85% of the time for the Software 505 System.

Table 13. System Agreement to SMBG within CGM Glucose Ranges (Software 505 Study).

CGM Glucose Ranges mg/dL	Number of Paired System-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent within 40/40% SMBG	Percent greater than 40/40% SMBG
Overall	2992	77%	87%	96%	99%	1%
40-60	221	73%	80%	87%	93%	7%
61-80	336	77%	85%	95%	99%	1%
81-180	1362	74%	85%	96%	99%	1%
181-300	826	80%	90%	97%	99%	1%
301-350	161	83%	93%	99%	100%	0%
351-400	86	90%	93%	98%	99%	1%

Note: CGM readings are within 40 to 400 mg/dL, inclusive.

For the analysis presented in Table 14, the Mean and Median Percent Difference and the Mean and Median Absolute Percent Difference were calculated to further illustrate the comparison between CGM readings and SMBG results.

Table 14. System Difference to SMBG within CGM Glucose Ranges (Software 505 Study).

CGM Glucose Ranges mg/dL	Number of Paired System-SMBG	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	2992	-2.6	-2.7	11.3	8.6
*40-60	221	-10.3	-6.0	13.0	8.0
*61-80	336	-4.0	-2.0	10.1	7.0
81-180	1362	-2.6	-3.1	11.4	8.9
181-300	826	-1.4	-2.0	9.5	7.4
301-350	161	0.0	0.0	8.3	6.0
351-400	86	3.9	3.2	8.1	6.7

* For CGM≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).
Note: CGM readings are within 40 to 400 mg/dL.

The Software 505 Study and Original Study demonstrate that the device is effective for tracking and trending to determine patterns in glucose levels, and for alerting patients when glucose values are approaching potentially dangerously high (hyperglycemic) and/or dangerously low (hypoglycemic) levels.

To communicate the updated accuracy information to users, data from both the Original Study and the Software 505 Study are included in the labeling.

3. Subgroup Analyses
CGM system performance was evaluated within study population subgroups, such as Arterialization at Calibration, Arterialization during clinic, diabetes type, body mass index (BMI), baseline A1C, gender and type of diabetes treatment.

Although not powered for analysis of subpopulations, no significant differences in performance were noted based on gender, BMI, diabetes type, baseline A1C, or type of diabetes medications.

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

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Clinical Chemistry and Clinical 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.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The results of the pivotal clinical study performed in this submission establish a reasonable assurance of safety and effectiveness with the Dexcom G4 Platinum System using the modified algorithm (Software 505) for detecting trends and tracking patterns when used as intended, as an adjuvant to blood glucose testing in subjects

with diabetes mellitus. The primary effectiveness measurements for this study were based on the performance evaluation of the Dexcom G4 Platinum System compared to the blood glucose values measured by the reference analyzer during in-clinic sessions that were obtained in the in-clinic sessions spanning the wear period of the sensor (days 1, 4, and 7).

The performance data presented above (Tables 3A, 4A, 5A, 6A, 7A, 8A, 9A, 10A, 11 to 14) support the effectiveness conclusions and established the accuracy across the claimed measuring range (40 to 400 mg/dL glucose), precision, and the claimed calibration frequency (calibrate every 12 hours), the 7 day wear period for the sensor, the alarms and alerts, and the number of readings displayed in the 7 day wear period.

The clinical study data demonstrate that the G4 PLATINUM CGM System with Software 505 was effective in the study population designed to be reflective of the intended use population.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory data (provided in the original PMA; P120005) as well as data collected in a clinical study conducted to support PMA approval as described above.

The following events are possible adverse device effects of inserting a sensor into your skin: local infection, inflammation, pain or discomfort, bleeding at the glucose sensor insertion site, bruising, itching, scarring or skin discoloration, hematoma, tape irritation, sensor or needle fracture during insertion, wear or removal. During the clinical studies the following device-related non-serious events were reported: Thirteen (13) AEs were reported, affecting 10 subjects. Twelve (12) AEs were related to skin irritation related to the device (erythema at adhesion area or needle insertion site). All of these were rated as 'Very slight'. One (1) AE was categorized as 'Other', possibly related to study. No infections occurred at either insertion or adhesive areas. AEs were transient, and resolved by the end of the subject's participation in the study or deemed on-going, but stable at study termination.

Per protocol, the mechanical integrity of each sensor was independently assessed after removal of the sensor from the subcutaneous adipose tissue. There were no reports of broken sensor wires, nor any sensor wire detachments from the sensor housing units.

No SAEs or UADEs were reported in the clinical studies. However, there are risks related to either an inaccurate sensor value outside of the patient's normal range or a false alert/alarm that results in performing an unnecessary additional blood glucose test to confirm the erroneous sensor reading. The risk of medical harm is, however, mitigated through labeling which emphasizes that patients should confirm all CGM readings prior to making treatment decisions.

There are risks due to missed alerts and false negative hypoglycemic and hyperglycemic readings related to patients not being alerted to the need to perform a fingerstick to detect hypoglycemia or hyperglycemia. Additionally, there is a risk associated with false alerts and false positive hypoglycemia and hyperglycemia readings related to the need to perform unnecessary fingersticks to confirm an erroneous low or high reading. However, since patients who only use blood glucose meters to manage their diabetes without the aid of a CGM would also be unaware of the need to perform additional testing to detect an abnormal blood sugar (unless they were exhibiting symptoms of an abnormal blood glucose), the risk of inaccurate results related to the use of this device is no greater than the risk of managing diabetes with a meter alone unless patients omit a blood glucose test that they would have otherwise performed if they were not using the sensor or the sensor was not reading within their target glucose range.

Inaccurate calculation of the rate of change of glucose by the CGM could prevent a patient from performing additional blood glucose tests or taking measures to stop a trend of increasing or decreasing glucose levels which could lead to serious hypoglycemia or hyperglycemia if no action is taken to stop these glucose trends. However as patients often do not test frequently enough with a meter to calculate the rate of change, this risk is not greater than with traditional glucose monitoring with a meter. Inaccurate estimation of the rate of change of glucose could also lead to unnecessary additional blood glucose tests or inappropriate measures to stop an incorrect trend of increasing or decreasing glucose level. However the risk of medical harm is limited to instances where the user relies on the rate of change calculated by the sensor without confirmation by a blood glucose meter. This risk is partially mitigated by the requirement for subjects to base treatment decisions on blood glucose levels.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above as well as the data collected in the original PMA (P120005).

This submission is for modification to the algorithm in the receiver of the G4 Platinum Sensor. The algorithm converts the sensor electrical signal to glucose values. The benefits and risks associated with the G4 System with Software 505 are unchanged from the Original G4 system. The sensor performance of the G4 System with Software 505 is effective for its intended use..

This device is intended to supplement self-monitoring of blood glucose to track and trend interstitial glucose levels as estimates of glucose excursions in the blood. The adjustable hypoglycemia and hyperglycemia alerts are intended to warn the patients that they need to test their blood sugar to see if they need to take action to treat or prevent a hypoglycemic or hyperglycemic event. Furthermore, CGM measurements,

which are performed every 5 minutes for 7 days via an indwelling sensor, do not require repeated performance of fingersticks with a lancet for each measurement as is required for each individual blood glucose measurement with a traditional glucose meter.

These functions are not feasible using traditional blood glucose monitoring as blood glucose meters only provide information about discrete, intermittent blood glucose levels and therefore are unable to provide information regarding patterns of glycemic excursions throughout the day and night when patients may be unable to test their blood glucose. Furthermore, real time knowledge of whether blood glucose is increasing or decreasing adds information unavailable by traditional discrete monitoring. This information regarding direction and rate of change can alert users that they need to take action to prevent hypoglycemia or hyperglycemia. The alert functions can notify users that they need to test their blood sugar to see if they need to take action to treat asymptomatic hypoglycemia or hyperglycemia before their blood glucose concentration reaches a dangerous level. This is especially helpful for individuals with hypoglycemia unawareness (these individuals may develop severe hypoglycemia with loss of consciousness, seizures, or rarely death without the normal warning symptoms), or during the night when subjects may have prolonged hypoglycemia that does not waken them which could proceed to severe hypoglycemia if not treated in time. Traditional blood glucose monitoring is not able to capture these potentially dangerous episodes of asymptomatic hypoglycemia. Therefore, this device provides significant benefit to users not possible with traditional glucose monitoring.

A minor risk of this device is that users may need to perform unnecessary fingersticks to evaluate their blood glucose when the CGM gives false positive hypoglycemic and hyperglycemic readings or alerts. There is a minor risk of skin irritation, inflammation, or infection due to either the sensor needle or the adhesive.

There is a risk of a sensor breakage leaving a sensor fragment under the skin. This event was reported infrequently with previously approved sensors. No sensor breakage was documented in this study. Reported sensor breakage rate with similar devices has been very low, however, and this study was not powered or designed to assess the rate of breakage, though all sensors were inspected for fracture after removal. The sensor has specifically been redesigned to decrease the risk of breakage.

There are risks due to missed alerts and false negative hypoglycemic and hyperglycemic readings related to patients not being alerted to the need to perform a fingerstick to detect hypoglycemia or hyperglycemia. There is a risk due to false alerts and false positive hypoglycemia and hyperglycemia readings related to the need to perform unnecessary fingersticks to confirm an erroneous low or high reading. Inaccurate calculation of the rate of change of glucose by the CGM could prevent a patient from performing additional blood glucose tests or taking measures to stop a trend of increasing or decreasing glucose levels which could lead to serious hypoglycemia or hyperglycemia if no action is taken to stop these glucose trends.

Inaccurate calculation of the rate of change of glucose could also lead to unnecessary additional blood glucose tests or inappropriate measures to stop a trend of increasing or decreasing glucose level which could result in hyperglycemia or hypoglycemia.

There is a risk related to off label use of the device if patients make decisions on diabetes management based on inaccurate sensor readings alone without confirmation by blood glucose testing.

The labeling advises patients that if their CGM reading does not correspond to their symptoms of high or low blood sugar, they should not rely on the CGM reading, but should perform a blood glucose measurement. Users are further advised that if there is a discrepancy between the CGM and the blood glucose result, the user should recalibrate the CGM to improve accuracy.

In conclusion, given the available information above, the data support that for detecting trends and tracking patterns in glucose levels, 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 System, as discussed above, outweigh the risks.

XIII. CDRH DECISION

CDRH issued an approval order on October 21, 2014. The final conditions of approval are cited in the approval order

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

XIV. 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.