510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K213131

B Applicant

Roche Diabetes Care, Inc.

C Proprietary and Established Names

Accu-Chek Guide Solo diabetes manager blood glucose monitoring system

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Glucose Test System	CH – Clinical Chemistry
NDC	Class II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	CH – Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in capillary whole blood drawn from the fingertip

C Type of Test:

Quantitative amperometric assay, glucose dehydrogenase (GDH-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

OTC Use:
The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is comprised of the Accu-Chek Guide Solo diabetes manager blood glucose meter, Accu-Chek Bolus Advisor and the Accu-Chek Guide test strips.

The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip. The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use), by individuals with diabetes at home as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is intended to be used by a single person and should not be shared. This Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Rx Use:
The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system is comprised of the Accu-Chek Guide Solo diabetes manager blood glucose meter, Accu-Chek Bolus Advisor and the Accu-Chek Guide test strips.

The Accu-Chek Bolus Advisor, as a component of the Accu-Chek Guide Solo diabetes manager, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data. Before its use, a physician or healthcare professional must activate the bolus calculator and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software. The Accu-Chek bolus advisor is intended for home use. The Accu-Chek Guide Solo diabetes manager steers the Accu-Chek Solo micropump.

C Special Conditions for Use Statement(s):

Rx and OTC

For single patient use only

Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

This system has not been tested at altitudes higher than 10,150 feet.

Meters and lancing devices should never be used by more than one person. Do not share them with anyone, including other family members, due to the risk of infection from bloodborne pathogens. Do not use on multiple patients!

Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

D Special Instrument Requirements:

Accu-Chek Guide Solo diabetes manager
Accu-Chek Solo Micropump System

IV Device/System Characteristics:

A Device Description:

The Accu-Chek Guide Solo diabetes manager blood glucose monitoring system consists of the Accu-Chek Guide Solo diabetes manager blood glucose meter, Accu-Chek Guide Test Strips and Accu-Chek Guide Control Solutions (Level 1 and Level 2, cleared in k160944). It is used for self-monitoring of blood glucose. The Accu-Chek Guide Test Strips and Accu-Chek Guide Control Solutions are purchased separately. The device is powered by a rechargeable battery and serves as a remote control and primary user interface for the Accu-Chek Solo micropump system (k213134).

All meter kits include a Carrying Case, User's Manual, Quick Reference Guide, Warranty Card and Logbook. Materials needed but not provided include a single user lancing device and sterile lancets.

B Principle of Operation:

The meter measures glucose amperometrically using an FAD-GDH enzyme located on the test strip, which converts the glucose in the blood to gluconolactone. The meter converts the measured current into blood glucose reading that is displayed on the meter's display. The sample and the environmental conditions are evaluated using AC and DC signals. The meter converts the measured current into blood glucose reading that is displayed on the meter's display.

C Instrument Description Information:

1. Instrument Name:

   Accu-Chek Guide Solo diabetes manager

2. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

   Capillary whole blood samples drawn from the fingertips. Samples are to be tested immediately upon collection.

4. Calibration:

   The meter does not require calibration by the user, it is factory calibrated.

5. Quality Control:

   Two levels of glucose control solutions are available for use with this system and can be purchased separately (Accu-Chek Guide Control Solutions, Level 1 and Level 2, cleared in k160944). Recommendations on when to test with control solutions are provided in the labeling. Acceptable ranges for each level of control solution are printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. The control solution readings are automatically marked by the meter as control results and are not included in the patient result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Accu-Chek Guide Blood Glucose Monitoring System
Accu-Chek Connect Diabetes Management App

B Predicate 510(k) Number(s):

K160944
K150910

C Comparison with Predicate(s):

Device & Predicate Device(s):	K213131	K160944
Device Trade Name	Accu-Chek Guide Solo diabetes manager glucose monitoring system	Accu-Chek Guide Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of glucose in fresh capillary whole blood samples.	Same

Control Solutions	2 Levels, aqueous solutions, shelf life of 24 months	Same
Strip Chemical Composition	Glucose Dehydrogenase (GDH/FAD)	Same
General Device Characteristic Differences		
Alternate Site Testing	No AST claim	Palm, Forearm, and Upper Arm
Batteries	Rechargeable lithium polymer battery	2 CR2032
Display	Capacitive color LCD multi-touch screen	Dot Matrix LCD

Device & Predicate Device(s):	K213131	K150910
Device Trade Name	Accu-Chek Guide Solo diabetes manager glucose monitoring system	Accu-Chek Connect Diabetes Management App
General Device Characteristic Similarities		
Intended Use/Indications For Use	Calculation of insulin dose or carbohydrate intake based on user-entered data.	Same
General Device Characteristic Differences		
Connected Devices	Accu-Chek Solo micropump system	Accu-Chek Aviva Connect Blood Glucose Meter

VI Standards/Guidance Documents Referenced:

FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance for Industry and Food and Drug Administration Staff. Issued on September 29, 2020.

ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

IEC 62304-1 Edition 1.1 2015-06 consolidated version-Medical device software- Software life cycle processes

CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)

IEC 60601-1-2 Edition 4.0 2014-02Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

AIM Standard 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

ANSI IEEEC63.27-2017American National Standard for Evaluation of Wireless Coexistence

AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run Precision (Repeatability):
A within-run precision study using 3 lots of Accu-Chek Guide Test Strips was performed. Venous blood was spiked to 8 concentrations (i.e. 20, 40, 80, 130, 200, 325, 450, and 550 mg/dL). For each sample concentration, 10 meters were used, with 10 measurements taken by each meter, and 3 lots tested (i.e. 100 measurements per concentration per lot). Glucose reference results were determined using a comparator method.

Results for the within- run precision study are summarized below:

Strip Lot	Target Glucose (mg/dL)	N	Mean Glucose (mg/dL)	SD (mg/dL)	CV (%)
1	20	100	13.6	1.1	8.4
2	20	100	14.1	0.9	6.7
3	20	100	14.0	1.1	8.2
Lots combined	20	300	13.9	1.1	7.9
1	40	100	38.2	1.3	3.3
2	40	100	37.8	1.3	3.3
3	40	100	38.5	1.2	3.2
Lots combined	40	300	38.2	1.3	3.4

1	80	100	86.3	1.5	1.8
2	80	100	86.0	1.6	1.9
3	80	100	87.7	1.5	1.8
Lots combined	80	300	86.6	1.7	2.0
1	130	100	136.4	2.8	2.0
2	130	100	135.4	2.5	1.8
3	130	100	136.1	2.6	1.9
Lots combined	130	300	136.0	2.6	1.9
1	200	100	221.2	4.8	2.2
2	200	100	220.2	4.2	1.9
3	200	100	222.9	5.4	2.4
Lots combined	200	300	221.4	5.0	2.2
1	325	100	364.0	7.0	1.9
2	325	100	361.8	7.3	2.0
3	325	100	364.0	8.4	2.3
Lots combined	325	300	363.3	7.6	2.1
1	450	100	460.4	9.6	2.1
2	450	100	452.2	7.2	1.6
3	450	100	460.1	11.6	2.5
Lots combined	450	300	457.6	10.4	2.3
1	550	100	554.9	11.4	2.0
2	550	100	543.8	11.3	2.1
3	550	100	556.7	15.5	2.8
Lots combined	550	300	551.8	14.0	2.5

Intermediate precision (Between Run):

Intermediate (between run) precision was evaluated using 3 lots of the Accu-Chek test strips performed on 6 levels of control solutions (i.e. Level 1:10-29 mg/dL, Level 2: 30-50 mg/dL, Level 3: 111-150 mg/dL, Level 4: 251-400 mg/dL, Levels 5 and 6: 501-600 mg/dL). The tests were conducted with 10 meters, 1 measurement per meter per day at the 5 different glucose ranges, for 10 days. Results for the intermediate precision study are summarized below:

Strip Lot	Control Level	N	Mean Glucose (mg/dL)	SD (mg/dL)	CV (%)
1	1	100	28.9	1.2	4.2
2	1	100	27.6	1.1	4.1
3	1	100	28.2	1.0	3.6
Lots combined	1	300	28.3	1.2	4.4
1	2	100	46.5	1.2	2.6
2	2	100	45.2	1.2	2.6
3	2	100	45.8	1.6	3.4
Lots combined	2	300	45.8	1.4	3.1
1	3	100	120.7	2.0	1.6
2	3	100	117.5	2.6	2.2
3	3	100	119.3	2.4	2.0
Lots combined	3	300	119.2	2.6	2.2
1	4	100	309.6	5.7	1.8

2	4	100	306.6	6.3	2.1
3	4	100	307.3	6.9	2.2
Lots combined	4	300	307.8	6.4	2.1
1	5	100	519.0	10.5	2.0
2	5	100	513.9	7.3	1.4
3	5	100	521.5	8.0	1.5
Lots combined	5	300	518.1	9.3	1.8
1	6	100	571.3	7.9	1.4
2	6	100	561.9	9.1	1.6
3	6	100	569.8	9.5	1.7
Lots combined	6	300	567.7	9.7	1.7

2. Linearity:

Linearity was evaluated using three reagent lots and 36 Accu-Chek Guide Solo diabetes manager blood glucose meters by testing venous blood samples spiked with glucose at concentrations ranging from 5.2 to 603.2 (5.2, 14, 38.8, 60.8, 89.7, 123.4, 155.7, 198.8, 289, 449.4, 603.2) mg/dL, as measured by the comparator method. One run (across all 36 meters) was performed with each sample using each of the strip lots. The values from the meter were compared with those obtained from the comparator method. The results from regression analysis are summarized below:

Test Strip Lot	Slope	Y-Intercept	R^2
1	0.97	0.0969	0.9983
2	0.95	0.51	0.9976
3	0.96	1.55	0.9983
All Lots Pooled	0.96	0.7189	0.9981

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. The meter will display "LO" when the result is less than 20 mg/dL and "HI" when result is greater than 600 mg/dL. The sponsor validated the "LO" and "HI" functions and demonstrated that they functioned as intended.

3. Analytical Specificity/Interference:

To assess potential interference the sponsor used a venous whole blood sample adjusted to 3 different glucose levels, split into a control sample and a test sample. Various endogenous and exogenous substances were then added to the test sample only. The % difference between the test and control sample was calculated and the concentration tested at which no significant interference was observed is presented in the table below:

Potential Interfering Substance	**Highest Concentration with no Significant Interference**
Acetaminophen	20 mg/dL
Ascorbic acid	6 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Cholesterol	500 mg/dL
Creatinine	30 mg/dL

Dopamine	0.09 mg/dL
Galactose	300 mg/dL
Gentisic Acid	1.8 mg/dL
Glutathione (reduced, L-Glutathione)	6.14 mg/dL
Hemoglobin	1000 mg/dL
Heparin	8000 U/dL
Ibuprofen	50 mg/dL
Lactitol	100 mg/dL
EDTA	360 mg/dL
Xylitol	200 mg/dL
L-Dopa	2 mg/dL
Maltitol	20.2 mg/dL
Maltose	685 mg/dL
Mannitol	1800 mg/dL
Methyl Dopa	2.25 mg/dL
Pyridinealdoxime Methiodide (PAM)	25 mg/dL
Salicylic Acid	60 mg/dL
Sorbitol	70 mg/dL
Tolazamide	200 mg/dL
Tolbutamide	100 mg/dL
Triglycerides	1800 mg/dL
Uric Acid	23.5 mg/dL
Xylose	10 mg/dL
Sodium	165 mmol/L
Isomalt	0.09 mg/dL

The sponsor has the following limitations in their labeling:

- Abnormally high concentrations (greater than 5 mg/dL) of ascorbic acid (vitamin C) may cause inaccurate results. High-dose vitamin C therapy that would result in abnormally high concentrations is typically prescribed by your healthcare professional. If you are not sure if this applies to you, please check with your healthcare professional.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate results. Xylose absorption testing is performed under the supervision of a healthcare professional. Ask your healthcare professional how long to wait after xylose testing before performing a blood glucose test.

4. Assay Reportable Range:

   20-600 mg/dL glucose

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability: The Accu-Chek Guide Solo diabetes Manager is traceable to the NIST SRM 917c glucose reference material.

Test Strip Stability: The protocols and acceptance criteria for the Accu-Chek Guide Blood Glucose test strips previously cleared in K160944 and found to be acceptable. The sponsor claims that both closed-vial (shelf life) and open-vial stability are up to 18 months when stored at the recommended storage temperatures of 39-86°F (4-30°C) and 10-90% RH. The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

   Please see the linearity section above (VII.A.2).

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See Lay-user study below (VII.C.3).

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Method Comparison/Lay User Performance study:

   To assess system accuracy, results from the Accu-Chek Guide Solo Blood Glucose Monitoring System were compared to a reference method, PCA-HK. Capillary samples from 350 participants with glucose concentrations ranging from 48 to 478 mg/dL glucose obtained

on the reference were measured using one of three test strip lots by a technician. Samples were tested using 3 meters and 3 test strip lots. Results are summarized in the tables below:

Glucose concentrations <75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/6 (100 %)	6/6 (100 %)	6/6 (100 %)

Glucose concentrations ≥ 75 mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
227/344 (66.0%)	318/344 (92.4%)	337/344 (98.0%)	342/344 (99.4%)

Glucose Concentrations for entire measuring range			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
233/350 (66.6 %)	324/350 (92.6 %)	343/350 (98.0 %)	348/350 (99.4 %)

Linear regression results for all strip lots tested (N=350):

$Y = 0.998x - 1.1$; $r^2=0.982$

Accuracy at Extreme Glucose Study:

A study to evaluate the performance of Accu-Chek Guide Solo Blood Glucose Monitoring System in the extreme lower and upper ends of the claimed range was performed using 59 altered samples with glucose concentrations below 80 mg/dL, and 61 altered samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested on Accu-Chek Guide Test Strips from 3 lots . The glucose concentrations in the samples ranged from 25.7-80.2 mg/dL on the lower end and 257.5 -600.1 mg/dL on the higher end, obtained using PCA-HK. Results are summarized below:

Extreme glucose accuracy for glucose concentrations <80 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
34/59 (57.6 %)	56/59 (94.9 %)	59/59 (100.0%)	59/59 (100.0%)

Extreme glucose accuracy for glucose concentrations >250mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
48/61 (78.7%)	61/61 (100.0%)	61/61 (100.0%)	61/61 (100.0%)

Usability:
At the end of the study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use in the User's Manual and the overall performance of the Accu-Chek Guide Solo diabetes manager blood glucose monitoring system.

Readability:
A Flesch-Kincaid readability assessment was conducted, and the results demonstrated that the Accu-Chek Guide Solo diabetes manager blood glucose monitoring system instructions for use are written for a reading level equivalent to or lower than 8th grade.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Based on published literature, the sponsor included the following in the labeling:

The ideal ranges for adults without diabetes are:

- less than 100 mg/dL before meals.
- less than 140 mg/dL within 2 hours after a meal.

References:

American Diabetes Association website; Diagnosing Diabetes and Learning about Prediabetes. http://www.diabetes.org/diabetes-basics/diagnosis/. Accessed April 22, 2019.

American Diabetes Association. 2. Classification and diagnosis of diabetes; Diabetes Care Standards of Medical Care in Diabetes- 2019. 2019; 42 (Suppl. 1): S13-S28.

Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the expert committee on the diagnosis and classification of diabetes mellitus. *Diabetes Care*. 2003 Jan;26 Suppl 1:S5-20. doi: 10.2337/diacare.26.2007.s5. PMID: 12502614.

F Other Supportive Instrument Performance Characteristics Data:

1) *Hematocrit Study:*

The protocols and acceptance criteria for the Accu-Chek Guide Solo Diabetes Manager blood glucose monitoring system are being leveraged from the previously cleared in K160944 and found to be acceptable. Briefly, different hematocrit levels was evaluated using whole blood samples with hematocrit levels of 10 – 65% (10, 15, 20, 25, 30, 35, 45, 50, 55, 60, 65 %) spiked with glucose to achieve target concentrations between 30-50, 51- 110, 111-144, 150-250, 251-400 mg/dL. A total of 10 replicates per run, per strip lot, per hematocrit level, and per glucose level were tested on 30 Accu-Chek Guide meters. The results demonstrated that the Accu-Chek Guide produces accurate results over the claimed hematocrit range of 10 – 65%.

2) *Altitude Study*:

The protocols and acceptance criteria for the Accu-Chek Guide Solo Diabetes Manager blood glucose monitoring system are being leveraged from the previously cleared in K160944 and found to be acceptable. Briefly, capillary fingerstick blood samples from 102 donors using three lots of Accu-Chek guide glucose test strips were tested at 10,150 feet above sea level using Accu-Chek Guide glucose meters. The meter results support the claims in the labeling that altitudes up to 10,150 feet have no significant effect on blood glucose measurement.

3) *Flex Studies:*

The following additional flex studies were performed with the Accu-Chek Guide Solo Diabetes Manager blood glucose monitoring system: system operating conditions testing, short sample detection, sample perturbation, intermittent sampling, and used test strips, drop, and shipping testing. The testing demonstrated that the device is robust under these conditions.

4) *Infection Control Studies*:

The device is intended for single patient use. Six Accu-Chek Guide Solo Diabetes Manager meters were subjected to 208 cleaning cycles, representing one cleaning per week for four years. Three meters were used for control/reference purposes that were not subjected to cleaning. The study demonstrated that cleaning the meter did not impact device durability or function. Disinfection efficacy studies were performed on the materials compromising the meter with the chosen disinfectant, Super Sani-Cloth (EPA registration #9480-4), demonstrating complete inactivation of hepatitis B virus (HBV). Robustness studies were also performed by the demonstrating that there was no change in performance or external materials of the meter after 208 cleaning and disinfection cycles (representing weekly disinfection for four years, the expected lifetime of the meter).

5) Test strip lot release criteria:

The test strip lot release protocols and criteria were reviewed and found to be acceptable.

6) Electromagnetic Compatibility (EMC) testing:

The sponsor provided documentation certifying that acceptable electrical safety and EMC testing had been performed and the system was found to be compliant.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.