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

I Background Information:

A 510(k) Number

K203711

B Applicant

Roche Diabetes Care Inc.

C Proprietary and Established Names

IWL2020 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

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in capillary whole blood from fingertip

C Type of Test:

Quantitative amperometric assay, glucose dehydrogenase (FAD-GDH)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The IWL2020 Blood Glucose Monitoring System is comprised of the IWL2020 meter and IWL2020 test strips.

The IWL2020 Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip as an aid in monitoring the effectiveness of glucose control.

The IWL2020 Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes at home.

The IWL2020 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.

Not for use in diagnosis or screening of diabetes mellitus.

Not for neonatal use.

The IWL2020 Blood Glucose Monitoring System is not indicated for Alternative Site Testing (AST).

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 the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

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 doctor. Ask your doctor how long to wait after xylose testing before performing a blood glucose test.

Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients with or without ketosis.

This system has not been tested at altitudes higher than 10,150 feet.
For single patient use only

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:

IWL2020 Meter

IV Device/System Characteristics:

A Device Description:

The IWL2020 Blood Glucose Monitoring System consists of the following:
- IWL2020 Meter (with two 3-volt lithium CR2032 batteries)
- IWL2020 Test Strips (may be sold separately)
- IWL2020 Control Solutions (Level 1 and Level 2, may be sold separately)
- Quick Start Guide

The IWL2020 Blood Glucose Monitoring System is a handheld device that incorporates features to aid in self-monitoring of blood glucose. The blood glucose results are displayed on the screen and stored in the meter's memory, and may also be transmitted via Bluetooth Low Energy (BLE) wireless communication.

B Principle of Operation:

The IWL2020 Blood Glucose Monitoring System quantitatively measures glucose amperometrically, and includes the enzyme on the test strip, FAD-dependent glucose dehydrogenase (GDH), which converts the glucose in the blood to gluconolactone. When a drop of whole blood is applied to the reaction cell on the test strip, glucose in the blood sample reacts in the presence of GDH-FAD and a mediator. The electrons generated during this reaction are detected by the meter. The magnitude of the resultant current is proportional to the concentration of glucose in the blood and is converted to a glucose concentration. The glucose concentration is displayed on the meter display for the user.

C Instrument Description Information:

1. Instrument Name:

   IWL2020 Meter

2. Specimen Identification:

   Capillary whole blood from the user's fingertip

3. Specimen Sampling and Handling:

   The system is intended to be used with capillary whole blood from the fingertip. The whole blood sample is applied directly to the test strip by capillary action. Samples are to be tested immediately upon collection.

4. Calibration:

   The IWL2020 meter is factory calibrated. No user calibration is required.

5. Quality Control:

   IWL2020 control solutions (Level 1 and Level 2) are for use with the IWL2020 Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly. The ranges for Level 1 and Level 2 controls are printed on the test strip container label. The meter automatically recognizes the difference between the control solution and blood. Instructions on when to perform a control test, details about the control solution, performing a control test, understanding out-of-range control results are provided in the meter manual. Control solution ranges are printed on the control solution package insert.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ACCU-CHEK Guide Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K160944

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203711	K160944
Device Trade Name	IWL2020 Blood Glucose Monitoring System	Accu-Chek Guide Blood Glucose Monitoring System

General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	Intended to quantitatively measure glucose (sugar) in fresh capillary whole blood samples as an aid in monitoring the effectiveness of glucose control.
Test principle	Same	Amperometric Detection
Sample volume	Same	600 nanoliters
Measurement Range	Same	20-600 mg/dL
General Device Characteristic Differences		
Site Testing	Fingertip	Palm, Forearm, and Upper Arm

VI Standards/Guidance Documents Referenced:

- ISO14971-Thrid edition 2019-12-"Medical Devices-Application of Risk Management to Medical Devices"
- IEC- 62304 Edition 1.1 2015-06-"Medical device software-Software life cycle processes"
- CLSI-EP06-A-"Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"
- IEC-61010-1 edition 3.0 2010-06-"Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability (within-run precision) studies were performed with contrived venous whole blood samples at 5 glucose concentration ranges using three test strip lots and 10 IWL2020 meters. Ten runs (vials) were performed on each sample with 10 replicates per strip lot resulting in a total of 100 replicates collected for each test strip lot and each glucose level tested. Results are summarized below:

Glucose Level	Strip Lot	Target Glucose (mg/dL)	N	Mean Glucose (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (30-50)	1	40	100	38.2	1.1	2.9
	2	40	100	38.0	1.1	2.8
	3	40	100	38.7	1.2	3.1
	Combined	40	300	38.3	1.2	3.0
Level 2 (51-110)	1	80	100	82.6	1.5	1.8
	2	80	100	83.2	1.7	2.0
	3	80	100	81.8	1.9	2.3
	Combined	80	300	82.5	1.8	2.2
Level 3 (111-150)	1	130	100	138.6	3.1	2.3
	2	130	100	140.5	2.4	1.7
	3	130	99	137.0	2.3	1.6
	Combined	130	299	138.7	3.0	2.1
Level 4 (151-250)	1	200	100	218.1	4.0	1.9
	2	200	100	219.3	3.7	1.7
	3	200	100	212.8	4.4	2.1
	Combined	200	300	216.7	4.9	2.3
Level 5 (251-400)	1	325	100	369.7	8.1	2.2
	2	325	100	370.9	8.4	2.3
	3	325	100	360.3	9.1	2.5
	Combined	325	300	367.0	9.8	2.7

Intermediate precision was evaluated using three levels of glucose control solutions. Each sample was measured in replicates of ten using ten IWL2020 meters, three lots of test strips over ten days, resulting in a total of 300 tests for each glucose level. Results are summarized below:

Glucose Level	Strip Lot	N	Mean Glucose (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (51-110)	1	100	44.5	1.3	2.8
	2	100	44.8	1.3	2.8
	3	100	44.0	1.4	3.2
	Combined	300	44.4	1.3	3.0
Level 2 (111-150)	1	100	113.3	3.0	2.7
	2	100	114.9	2.8	2.5
	3	100	112.5	2.5	2.3
	Combined	300	113.6	3.0	2.6
Level 3 (251-400)	1	100	291.7	6.6	2.3
	2	100	294.8	5.9	2.0
	3	100	289.4	6.5	2.2
	Combined	300	291.9	6.7	2.3

2. Linearity:

Linearity was evaluated using three test strip lots and 36 IWL2020 meters by testing 11 venous whole blood samples with glucose concentrations ranging from 5.6 to 627.8 mg/dL (5.6, 14.8, 37.7, 58.4, 94.2, 127.1, 153.1, 211.0, 282.0, 471.6, 627.8 mg/dL). One run (across all 36 meters) was performed with each sample type using each of the strip lots. The values from the IWL2020 meter were compared with those obtained from the comparator method (hexokinase reagent on the Roche Cobas c 501 analyzer). The results from regression analysis are summarized below:

Test strip lot #1: $y=1.080\ x+2.3817$; $R^2 = 0.9985$
Test strip lot #2: $y=1.06\ x+1.0307$; $R^2 = 0.9987$
Test strip lot #3: $y=1.06\ x+0.6098$; $R^2 = 0.9986$

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 venous whole blood samples adjusted to three different glucose levels of 60, 120, 250 mg/dL, split into control sample and test samples. 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 (defined as ± 10 mg/dL for glucose concentrations < 100 mg/dL and ± 10% for glucose concentrations ≥ 100 mg/dL) was observed is presented in the table below:

Potential Interfering Substance	Highest concentration at which no significant interference is observed (mg/dL)
Acetaminophen	20
Ascorbic acid	5
Bilirubin (unconjugated)	60
Cholesterol	500
Creatinine	30
Dopamine	0.09
Galactose	300
Gentisic Acid	1.8
Glutathione	6.14
Hemoglobin	1000
Heparin	8000 U/dL
Ibuprofen	50
Lactitol	100

Potential Interfering Substance	Highest concentration at which no significant interference is observed (mg/dL)
Isomalt	0.09

Potential Interfering Substance	Highest concentration at which no significant interference is observed (mg/dL)
Sodium	165 mmol/L
Xylitol	200
L-Dopa	2
Maltitol	20.2
Maltose	685
Mannitol	1800
Methyl Dopa	1.5
Pyridine aldoxime Methiodide (PAM)	25
Salicylic Acid	60
Sorbitol	70
Tolazamide	200
Tolbutamide	100
Triglycerides	1800
Uric Acid	23.5
Xylose	10
EDTA	360
Sorbitol	70

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 doctor. Ask your doctor how long to wait after xylose testing before performing a blood glucose test.

4. Assay Reportable Range:

The results of the linearity study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL.

5. Traceability, Stability, Expected Values:

   Traceability: According to the sponsor, the IWL2020 Blood Glucose Monitoring System is traceable to the NIST Standard Reference Material (SRM) 917 glucose reference material. A method comparison was performed using the IWL2020 Blood Glucose Monitoring System and hexokinase reagent on the Roche Cobas c 501 analyzer as the comparator method (see section B.1).

   Test Strip Stability: IWL2020 Test Strip stability assessed using real time stability studies. The protocols and acceptance criteria were reviewed and found to be acceptable to support the labeling claims that the test strips are stable both closed (shelf life) and open-vial for within 18 months when stored at the recommended storage temperatures of 39-86°F (4-30°C) and 10-90% relative humidity (RH). The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

   The reportable range for the IWL2020 Blood Glucose Monitoring System is 20 to 600 mg/dL.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   See method comparison study (section VII.C3).

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See section VII.C3.

2. Matrix Comparison:

   Not applicable. Only for use with capillary whole blood sample collected from the fingertip.

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):

To assess the performance of the IWL2020 Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 350 lay user participants. Users obtained their own fingertip capillary sample and performed a glucose test using only the labeling instructions provided in English. Three test strip lots were used in the study. Results were analyzed by comparing blood glucose results from finger stick samples using the IWL2020 meter, obtained by the lay users, against results obtained on the comparator method (hexokinase reagent on the Roche Cobas c 501 analyzer) with samples obtained by a trained technician. The samples ranged from 49 to 395 mg/dL as measured by the comparator method. All samples used were unaltered. The results are summarized in the tables below:

Results from glucose concentrations less than 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%
3/6 (50 %)	5/6 (83 %)	6/6 (100%)

Results from glucose concentrations greater than 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20 %
217/344 (63%)	304/344 (88%)	331/344 (96%)	340/344 (99%)

Regression results:

Slope	Y-intercept	R^2
0.974	4.8	0.975

Readability:

A Flesch-Kincaid readability assessment was conducted on the IWL2020 Meter Manual, IWL2020 Test Strip Insert, and Quick Start Guide and the results demonstrated that the labeling was written at lower than 8th grade level.

Accuracy at Extreme Glucose Values:

An additional study was conducted to assess the accuracy of the IWL2020 Blood Glucose Monitoring System at the extreme low and high ends of the claimed measurement range using 46 capillary whole blood samples with glucose concentrations below 80 mg/dL, and 56 samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested with the IWL2020 Blood Glucose Monitoring System with test strips from 3 lots and compared to the results obtained using the comparator method (hexokinase reagent on the Roche Cobas c 501 analyzer). The glucose concentrations in the samples ranged from 22 – 590 mg/dL, as measured by the comparator method. Results are summarized below:

Accuracy results for Glucose concentrations less than 80 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
33/51 (65%)	48/51 (94%)	51/51 (100%)	51/51 (100%)

Accuracy results for Glucose concentrations greater than 250 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
39/50 (78%)	49/50 (98%)	50/50 (100%)	50/50 (100%)

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The following is included in the labeling:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

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

F Other Supportive Instrument Performance Characteristics Data:

1) Hematocrit Study: The effect of different hematocrit levels on the performance of the IWL2020 Blood Glucose Monitoring System was evaluated using contrived venous whole blood samples with hematocrit levels of 10 – 65% (10, 15, 20, 25, 30, 35, 42 (nominal), 45, 50, 55, 60, 65, 70%) spiked with glucose to achieve target concentrations between 30-50, 51-110, 111-150, 151-250, 251-400mg/dL. A total of 90 replicates per sample were performed on IWL2020 Blood Glucose Monitor and 3 test strip lots and the results on the candidate system were compared to comparator method (hexokinase reagent on the Roche Cobas c 501 analyzer). The results demonstrated that the IWL2020 Blood Glucose Monitoring System performs as intended with samples containing hematocrit concentrations spanning the claimed hematocrit range of 10 – 65%.

2) Altitude Study: To evaluate the effects of altitude on the IWL2020 Blood Glucose Monitoring System results, contrived venous whole blood samples were altered to five glucose concentrations (60, 110, 160, 350 and 500 mg/dL) and tested at 10,000 ft feet above sea level. Each venous whole blood glucose concentration was tested in duplicate using two strip lots and five glucose meters per strip lot. The meter results (20 glucose measurements for each glucose concentration) were compared to those obtained with the comparator method (hexokinase reagent on the Roche Cobas c 501 analyzer, tested at 719 ft). The results support the claims that the system functions as intended at altitudes up to the claimed

altitude of 10,000 feet.

3) System Operating Conditions Testing: To evaluate device performance over varying operating temperature and humidity conditions, contrived venous whole blood samples at glucose concentrations (60-80, 105-135, and 225-275 mg/dL) were tested at temperatures ranging from 4-45°C (39.2-113°F)and relative humidity from 10-90%. Conditions tested included 4°C(39.2°F)/30% (relative humidity, r.h.), 4°C(39.2°F)/90% r.h., 10°C(50°F)/10% r.h., 28°C(82.4°F)/90% r.h., 45°C(113°F)/10% r.h., and 45°C(113°F)/36% r.h, and meter results compared to the comparator method. The results support the claimed range of operating conditions: 6-44°C (42.8-111.2°F) and 10-90% relative humidity.

4) Flex Studies: Short sample detection, error codes for samples outside the measuring range, sample perturbation, testing with used test strips, intermittent sampling was completed. The testing performed demonstrated that the device is robust to short sample detection, sample perturbation, testing with used test strips, intermittent sampling, and that an error message is returned to the user if a used test strip is inserted into the meter.

5) Infection Control Studies: The device is intended for single patient use. A cleaning study was performed by cleaning the meter with mild dishwashing liquid detergent and water. Three test meters were subjected to 260 cleaning cycles, representing one cleaning per week for five 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). Robustness studies were also performed by the demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles (representing weekly disinfection for five years, the expected lifetime of the meter).

6) The sponsor has provided appropriate documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed with the candidate device, and that the system was found to be compliant.

7) Test strip lot release criteria: The test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling does support the finding of substantial equivalence for this device.

IX Conclusion:

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