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

I Background Information:

A 510(k) Number

K252323

B Applicant

Roche Diagnostics

C Proprietary and Established Names

cobas® pulse blood glucose monitoring system

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PZI	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) for a modified device, tracked as K252323 and CW250013, to add venous whole blood as a new sample type to the device previously cleared in K220272 and granted CLIA Waiver by application in CW220002.

B Measurand:

Glucose

C Type of Test:

Quantitative amperometric assay for blood glucose (FAD-dependent glucose dehydrogenase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The cobas® pulse blood glucose monitoring system consists of the cobas® pulse instrument and the cobas® GLU test strips.

This system is intended for in vitro diagnostic, point of care, multiple-patient use within professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The cobas® GLU test strips provide an in vitro diagnostic test that quantitatively measures glucose in venous whole blood, arterial whole blood, neonate arterial whole blood, or neonate heel stick whole blood samples, on the cobas® pulse system.

For neonate heel stick, the system should only be used with single-use, auto-disabling lancing devices.

This system is not intended for use with capillary fingerstick, neonate cord blood specimens or neonate venous specimens.

This system is not intended for screening or diagnosis of diabetes, but is indicated for use in determining dysglycemia.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- For in vitro diagnostic use only
- This system is not intended for use with capillary finger stick or neonate cord blood specimens.
  *See section VII.C.3 for additional information on sample limitations.
- Not for alternative site testing (AST)
- This system is not intended for screening or diagnosis of diabetes.
- Only use fresh whole blood for neonate heel stick or whole blood collected in lithium heparin collection devices for venous, arterial, neonate arterial, or neonate heel stick whole blood.
- Use only an auto-disabling single-use lancing devices for heel stick samples.
- Take caution to clear venous and arterial lines before the blood sample is obtained and applied to the test strip.
- Use only lithium heparin anticoagulant for blood collection.
- Altitudes above 14,107 feet (4300 meters) above sea level have not been evaluated.

D Special Instrument Requirements:

cobas® pulse instrument

IV Device/System Characteristics:

A Device Description:

The cobas® pulse blood glucose monitoring system consists of a hand-held, battery powered cobas® pulse instrument, single use cobas® GLU test strips, instrument charging station, quick reference guide and user guide for CLIA waived users as well as cobas® GLU test strip insert and user assistance guide for non-CLIA waived users. The cobas® GLU Linearity Kit and GLU QC kit are sold separately.

B Principle of Operation:

The detection chemistry used by the cobas® pulse blood glucose monitoring system for the blood glucose result is FAD-dependent glucose dehydrogenase (FAD-GDH). When the blood is applied to the test strip, the blood induces a chemical reaction which produces a current that is transmitted through the electrodes to the instrument. The magnitude of the resultant current is proportional to the glucose concentration in the sample. The detected current signal is then calculated by the meter and the glucose concentration is then displayed on the meter. The meter reports plasma equivalent glucose concentrations.

C Instrument Description Information:

1. Instrument Name:

   cobas® pulse instrument

2. Specimen Identification:

   Fresh whole blood from neonate heel stick or whole blood collected in lithium heparin collection devices for venous, arterial, neonate arterial, or neonate heel stick whole blood can be used with this test system. The meter contains a laser barcode scanner that allows for scanning patient identification information that may also be entered manually. The meter prompts the user to choose from a dropdown menu of sample types prior to testing.

3. Specimen Sampling and Handling:

   All samples must be tested immediately upon collection.

4. Calibration:

   The System does not require calibration by the end-user. Each lot contains calibration information that is uploaded into the instrument. When the test strip is inserted into the instrument, the instrument reads the test strip lot information from the strip that includes the calibration and expiration information for that test strip lot.

5. Quality Control:

The cobas® GLU QC kit control solutions are aqueous solutions available at two different glucose levels (Level 1 and Level 2). Instructions on when to perform quality control testing using both levels are included in the labeling. It is recommended to run both levels of quality controls at least once every 24 hours of patient testing and when one of the following occurs:

- the first time before using the instrument for patient testing,
- the first time the instrument is used by the operator,
- at shorter QC intervals if established by the workplace,
- when a new test strip container is opened,
- if there is a doubt about patient's glucose result,
- to test correct performance of the system,
- if the instrument was dropped,
- when other problems are suspected or identified (e.g., instrument outside of environmental conditions)

If the quality control testing using both QC levels is not performed when required as described in the labeling, the user is cautioned that a QC lockout is implemented, and blood glucose cannot be tested until the QC tests are run successfully. The meter displays a pass or fail result once both QC tests are performed. The acceptable ranges are communicated to the meter by the user scanning the barcode on the QC bottle. The user is cautioned not to use the meter and to contact the system administrator if the quality control test fails after repeating the QC test.

V Substantial Equivalence Information:

A Predicate Device Name(s):
StatStrip Glucose Hospital Meter System

B Predicate 510(k) Number(s):
K181043

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252323	K181043
Device Trade Name	cobas® pulse blood glucose monitoring system	StatStrip Glucose Hospital Meter System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative determination of glucose for use in determining dysglycemia in professional healthcare	Same

	settings.	
Measuring Range	10 to 600 mg/dL	Same
General Device Characteristic Differences		
Enzyme	FAD-dependent glucose dehydrogenase	Glucose oxidase
Sample Types	Venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick whole blood	Capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens

VI Standards/Guidance Documents Referenced:

CLSI EP09c 3rd edition. Measurement Procedure Comparison and Bias Estimation Using Patient Samples.

FDA Guidance "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use" - September 29, 2020

VII Performance Characteristics (if/when applicable):

The sponsor has made no technological, material, performance, or physical design changes from the device cleared in K220272. Therefore, the sponsor is leveraging analytical performance studies and flex studies from K220272 to support the function of the candidate device.

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K220272.

2. Linearity:

   Previously established in K220272.

3. Analytical Specificity/Interference:

   Previously established in K220272.

4. Assay Reportable Range:

   The reportable range is 10 to 600 mg/dL.

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

Traceability
Each measurement result is traceable to the NIST SRM 917 glucose reference material. A method comparison was performed using the candidate device and the Roche Glucose HK Gen.3 assay on the cobas® 6000 system as the comparator method (see section VII.C.3 below).

Test Strip Stability
Previously established in K220272. The labeling claims a 24-month closed vial shelf life and open vial use life when stored at 4 to 30°C (39 to 86°F) and relative humidity of 10 to 90%. The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

See Section C.3. Other Clinical Supportive Data.

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

See Section VII.C.3. Other Clinical Supportive Data.

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):

The performance of the cobas® pulse glucose monitoring system was assessed in professional healthcare settings using lithium heparin venous samples from 643 patients (571 adult and 72 pediatric). The study was conducted at 7 clinical sites and included patients from the general ward, operating rooms, emergency rooms, medical intensive care units, surgical intensive care units, pediatric intensive care units, urgent care clinics, and outpatient clinics. Results from the cobas® pulse glucose monitoring system were obtained by a total of 28 untrained operators.

Venous samples from patients (1 to over 81 years of age) were analyzed using a total of 3 different test strip lots. The glucose levels of the patient samples (according to the comparator) ranged from 26.1 to 482.6 mg/dL for all venous samples (156 samples <80 mg/dL and 14 samples >300 mg/dL). In addition to glucose levels, patient conditions, medication information, pO2, sodium, and hematocrit levels were collected during the study. The study included 665 unique patient conditions receiving a total of 616 medications representing 73 parent drug classes (see patient conditions and medication tables below).

The results of the cobas® pulse glucose monitoring system were compared with those obtained on the comparator and are as follows:

Venous Whole Blood

Glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
93/110 (84.5%)	109/110 (99.1%)	110/110 (100.0%)	110/110 (100.0%)	0/110 (0.0%)

Glucose concentrations ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
444/533 (83.3%)	524/533 (98.3%)	529/533 (99.2%)	533/533 (100.0%)	533/533 (100.0%)	0/533 (0.0%)

Regression Analysis		
Slope	y-intercept	R^2-value
1.008	-1.60	0.994

Usability Assessment/Operator Questionnaire

Upon completion of the clinical studies, operators completed a questionnaire to evaluate the ease of understanding of the test procedure. The participants found the cobas® pulse glucose monitoring system easy to use and the instructions in the user manual and quick reference guide are clear and easy to follow.

A readability assessment demonstrated that the quick reference guide and the instructions for the CLIA waived user in the user manual were written at a 7th grade reading level.

Patient Conditions and Medication

For all venous patients combined, there were a total of 665 unique patient conditions observed among the study subjects and 616 different medications administered to study subjects within 24 hours of blood draw. A summary of the medications and diagnosis for each sample type is shown below:

Sample Type	Number of Patients	Different Medications	Medication Classes	Different Diagnoses	System Organ Classes
Venous	643	616	73	665	26

The number of patients in the study by condition (organ classes) and medication classes are detailed below:

Patient Conditions

System Organ Class	Number of Patients
Blood and lymphatic system disorders	44
Cardiac disorders	128
Congenital, familial and genetic disorders	28
Ear and labyrinth disorders	15
Endocrine disorders	48
Eye disorders	19
Gastrointestinal disorders	135
General disorders and administration site conditions	38
Hepatobiliary disorders	13
Immune system disorders	29
Infections and infestations	107
Injury, poisoning and procedural complications	112
Investigations (laboratory testing and diagnostic procedures)	77
Metabolism and nutrition disorders	245
Musculoskeletal and connective tissue disorders	106
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	52
Nervous system disorders	153
Pregnancy, puerperium and perinatal conditions	9
Psychiatric disorders	179
Renal and urinary disorders	51
Reproductive system and breast disorders	25
Respiratory, thoracic and mediastinal disorders	119
Skin and subcutaneous tissue disorders	29
Social circumstances	11
Surgical and medical procedures	50

System Organ Class	Number of Patients
Vascular disorders	193

Medications

Medication Class	Number of Patients
Agents acting on the renin-angiotensin system	66
All other non-therapeutic products	2
All other therapeutic products	12
Analgesics	355
Anesthetics	94
Anthelmintics	1
Anti-acne preparations	1
Anti-parkinson drugs	9
Antianemic preparations	39
Antibacterials for systemic use	152
Antibiotics and chemotherapeutics dermatological use	15
Antidiarrheals, intestinal antiinflammatory/ antiinfective	5
Antiemetics and antinauseants	64
Antiepileptics	30
Antifungals for dermatological use	2
Antigout preparations	6
Antihemorrhagics	7
Antihistamines for systemic use	46
Antihypertensives	27
Antiinflammatory and antirheumatic products	56
Antimycotics for systemic use	17
Antineoplastic agents	2
Antipruritics, incl. Antihistamines, anesthetics, etc.	30
Antiseptics and disinfectants	4
Antithrombotic agents	206
Antivirals for systemic use	6
Beta blocking agents	73
Bile and liver therapy	3
Blood substitutes and perfusion solutions	266
Calcium channel blockers	25
Cardiac therapy	78
Contrast media	37
Corticosteroids for systemic use	25
Corticosteroids, dermatological preparations	3
Cough and cold preparations	9
Digestives, incl. Enzymes	1
Diuretics	64
Drugs for acid related disorders	147
Drugs for constipation	166
Drugs for functional gastrointestinal disorders	8
Drugs for obstructive airway diseases	83
Drugs in treatment of bone diseases	2

Medication Class	Number of Patients
Drugs used in diabetes	196
Emollients and protectives	9
Endocrine therapy	1
General nutrients	10
Immunosuppressants	10
Lipid modifying agents	117
Mineral supplements	83
Muscle relaxants	104
Nasal preparations	14
Ophthalmological and otological preparations	1
Ophthalmologicals	16
Other alimentary tract and metabolism products	14
Other dermatological preparations	1
Other hematological agents	1
Other nervous system drugs	19
Otologicals	1
Pancreatic hormones	4
Pituitary and hypothalamic hormones and analogues	7
Psychoanaleptics	94
Psycholeptics	125
Sex hormones and modulators of the genital system	13
Stomatological preparations	17
Throat preparations	2
Thyroid therapy	45
Topical products for joint and muscular pain	2
Urologicals	30
Vaccines	11
Vitamins	120

Accuracy at extreme glucose concentrations
Previously established in K220272.

Capillary Fingerstick Whole Blood Limitations
The sponsor includes limitations against the use of the cobas® pulse glucose monitoring system with capillary fingerstick whole blood. The labeling states the following limitations:

- This system is not intended for use with capillary finger stick whole blood, neonate cord blood specimens or neonate venous specimens.

- In comparing capillary whole blood glucose measurements using the cobas® pulse to venous plasma measurements using the comparator method, a large percentage of samples had significant bias to the comparator method.

These limitations were put in place due to risks posed by the performance of cobas® pulse glucose monitoring system with capillary fingerstick samples. The results of this device were compared with those obtained on the comparator method and are as follows:

For capillary fingerstick samples, 54.5% (12/22) of samples with glucose concentrations <75 mg/dL were within ±12 mg/dL and 45.5% (10/22) exceeded a difference of ±15 mg/dL relative to the comparator method result. Additionally, for capillary fingerstick samples with glucose concentrations ≥75 mg/dL, 82.2% (562/684) of the samples were within ±12 mg/dL and 7.0% (48/684) exceeded a difference of ±20% relative to the comparator method results.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following in the labeling:

The normal fasting serum and plasma glucose levels for an adult without diabetes is between 74-100 mg/dL.[1,2] The normal glucose level for an adult without diabetes two hours post-meal is less than 140 mg/dL.[2]

References:

1. Tietz (2018) Textbook of Clinical Chemistry and Molecular Diagnostics, 6th edition, ISBN:978-0-323-35921-4.
2. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S19–S40.

F Other Supportive Instrument Performance Characteristics Data:

Previously established in K220272.

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.