

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

A. 510(k) Number:

k090332

B. Purpose for Submission:

New glucose test strips (glucose meter itself is unchanged)

C. Measurand:

Whole blood Glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:

ARKRAY USA

F. Proprietary and Established Names:

Assure Pro Blood Glucose Monitoring System

Assure Dose Control Solution

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Blood Glucose Test System

21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II

Class I, reserved

3. Product codes:

NBW, Blood Glucose Test System, Over-the-Counter

CGA, Glucose Oxidase, Glucose

JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

Assure Pro Blood Glucose Monitoring System:

The Assure Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The Assure Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Assure Pro Blood Glucose Meter:

The Assure Pro Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Pro Blood Glucose Test Strips:

Assure Pro test strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips when used with the Assure Pro Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use in home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Dose CONTROL:

For use with Assure Pro Blood Glucose Meter and Assure Pro Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in two levels – Level 1 (Normal) and Level 2 (High).

3. Special conditions for use statement(s):

- Not intended for diagnosis of diabetes mellitus
- For in vitro diagnostic use only
- Not intended for use on neonates
- Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients

4. Special instrument requirements:

Assure Pro Blood Glucose meter

I. Device Description:

The Assure Pro Blood Glucose Monitoring System consists of a meter, test strips, and two levels of control solutions. It uses biosensor technology to produce a quantitative glucose concentration from whole blood samples from the fingertip. Users are instructed to code the meter using the supplied code chip when first used and with each new box of test strips.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Assure Pro Glucose Monitoring System

2. Predicate 510(k) number(s):

k053079

3. Comparison with predicate:

Similarities		
Item	Device (Assure Pro meter with new test strips)	Predicate (Assure Pro meter with predicate test strips)
Sample	Same	Capillary Whole Blood from Fingertip
Code Chip	Same	Required
Test Time	Same	10 seconds
Reference	Same	Plasma
Control Solutions	Same	Two Levels Supplied

Similarities		
Item	Device (Assure Pro meter with new test strips)	Predicate (Assure Pro meter with predicate test strips)
Operating Temperature Range	Same	50 – 104° F
Hematocrit Range	Same	30 – 55%
Maximum Altitude	Same	10, 000 feet

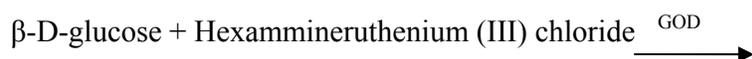
Differences		
Item	Device	Predicate
Minimum Sample Volume	0.5 µL	1 µL
Double Dosing Capability	No	Yes
Enzyme and Associated Reagents	Glucose Oxidase (<i>Aspergillus niger</i> sourced) and Hexammineruthenium (III) chloride	Glucose Oxidase (<i>Aspergillus niger</i> sourced)

K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP-07-A2, Interference Testing in Clinical Chemistry, 2005
- CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Methods, 2003
- ISO 15197, In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003

L. Test Principle:

The sample (whole blood) is drawn by capillary action at the tip of the test strip. Glucose in the sample reacts with glucose oxidase (GOD) and Hexaammineruthenium (III) chloride in the test strip. This produces Hexaammineruthenium (II) chloride. Hexaammineruthenium (II) chloride is produced in proportion to the glucose concentration of the blood sample. Oxidation of the Hexaammineruthenium (II) chloride produces an electric current. The meter converts the current to the glucose concentration and displays it as the test result:



M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Testing was performed consistent with ISO 15197 using fresh venous whole blood obtained from several non-diabetic volunteers and adjusted to a pO₂ of 60 to 80 mm Hg and hematocrit of 42%. The whole blood was spiked to obtain 5 glucose concentrations encompassing the 20-600 mg/dL range.

Within-Day precision tests consisted of 10 measurements of each of the five spiked whole blood glucose samples using 10 meters for each sample for a total of 500 measurements. The within-run precision for all meters and concentrations tested was as follows:

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
41.0	2.33	5.67
83.6	2.85	3.41
125.0	3.08	2.47
208.9	6.20	2.97
344.5	10.64	3.09

The Day to Day precision testing was performed using three glucose levels of control solutions; ten individual users performed this evaluation using ten meters over a period of ten days. This was repeated with three lots of test strips. A total of nine hundred test strips were used from more than ten vials of each of the three different lots of the test strips.

Lot A			
Level	Low	Mid	High
Mean	44.39	116.06	352.00
Standard Deviation (mg/dL)	0.84	1.33	7.79
Coefficient of Variation (%)	1.89	1.15	2.21

Lot B			
Level	Low	Mid	High
Mean	45.71	119.21	355.95
Standard Deviation (mg/dL)	0.98	2.67	7.73
Coefficient of Variation (%)	2.14	2.24	2.17

Lot C			
Level	Low	Mid	High
Mean	43.26	119.44	360.77
Standard Deviation (mg/dL)	0.87	3.66	9.05
Coefficient of Variation (%)	2.01	3.06	2.51

b. Linearity/assay reportable range:

The measuring range of the device is 20-600 mg/dL. A linearity study was conducted consistent with CLSI EP6-A using venous whole blood collected in a 10mL vacuum sample tube. Glucose was adjusted to 11 concentration levels ranging from 13 to 708 mg/dL (The Lo and Hi detection was disabled for this testing). Ten measurements were taken at each glucose concentration. The linear regression line for three lots was:

$$y = 0.9926x + 2.6, r^2 = 0.9975$$

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The controls supplied with this device were previously cleared under k053079.

Shelf life studies show that the unopened test strips have a twenty-four month life-span and a three month shelf-life once a vial of strips is opened.

d. Detection limit:

The detection limit is 20 mg/dL. See linearity/assay reportable range above.

e. Analytical specificity:

A total of 15 readings were taken for each glucose level and concentration of interferent (5 unique test strips per each of 3 lots). Three glucose levels were tested for each interferent including a low (50 – 80 mg/dL range), medium (125 – 160 mg/dL range), and high (310 – 400 mg/dL range). Bias was calculated as the mean difference in glucose reading between the test and control concentration groups.

Standard deviations and 95% confidence intervals (CIs) for the mean bias were also calculated. Percent bias was calculated as the bias divided by the mean glucose level at the control concentration. Standard deviations and 95% CIs for percent bias were also reported.

For glucose levels less than 75 mg/dL, the sponsor defined acceptable bias as when the lower bound of the 95% CI for bias was ≥ -10 mg/dL and the upper bound was ≤ 10 mg/dL. For glucose levels 75 mg/dL, the sponsor defined acceptable bias as when the lower bound of the 95% CI for percent bias was $\geq -10\%$ and the upper bound was $\leq 10\%$.

Based on these criteria, the following substances were found to interfere:

Ascorbic Acid at 6 mg/dL
Dopamine at 0.09 mg/dL
Ephedrine at 0.04 mg/dL

Interferents are noted in the labeling as follows:

Ascorbic acid (Vitamin C), when occurring in normal blood or normal therapeutic concentrations, does not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.

Externally taken drugs dopamine and ephedrine will not interfere with blood glucose results when taken at therapeutic concentrations. However, abnormally high concentrations in blood may cause inaccurate results.

Using the same criteria, the following substances were found not to interfere:

Acetaminophen up to 20 mg/dL
Acetyl-Salicylic Acid up to 65 mg/dL
Cholesterol up to 665 mg/dL
Conjugated bilirubin up to 40 mg/dL
Creatinine up to 5.0 mg/dL
Fructose up to 30 mg/dL
Galactose up to 60 mg/dL
Gentisic Acid up to 1.8 mg/dL
Glutathione up to 3.00 mmol/L
Hemoglobin up to 735 mg/dL
Ibuprofen up to 50 mg/dL
L-DOPA up to 13 mg/dL
Lactose up to 30 mg/dL
Maltose up to 450 mg/dL
Maltotetraose up to 450 mg/dL
Maltotriose up to 240 mg/dL
Mannitol up to 800 mg/dL
Mannose up to 16 mg/dL
Methyl-L-Dopa up to 1.5 mg/dL
Salicylic Acid up to 50 mg/dL
Sorbitol up to 10 mg/dL
Tetracycline up to 1.5 mg/dL
Tolazamide up to 70 mg/dL
Triglyceride up to 3300 mg/dL
Trubutamide up to 64 mg/dL
Unconjugated Bilirubin up to 20 mg/dL
Urea up to 280 mg/dL

Uric Acid up to 21 mg/dL
Warfarin up to 1.0 mg/dL
Xylitol up to 50 mg/dL
Xylose up to 80 mg/dL

Altitude Study

A study was conducted to evaluate the effect of altitude on the Arkray Assure Pro meter using the new glucose strips. Venous blood was collected from a donor in a sodium heparin tube and allowed to undergo glycolysis at room temperature to lower the endogenous glucose to approximately 40 mg/dL. The sample was separated into 4 aliquots and spiked with glucose to levels of approximately 60, 125, 300 and 450 mg/dL. After spiking to obtain the 4 different levels, the glucose values were confirmed with the YSI glucose analyzer. The tests were performed at 967 feet and at 10,000 feet aboard an unpressurized small airplane. At each location, venous blood at each of the 4 levels of glucose was tested on the same test strip lot. The meter readings obtained at 10,000 feet were compared to the meter readings at sea level and the % bias was determined at each level.

Results recovered within ± 15 mg/dL at blood glucose levels of < 75 mg/dL and $\pm 15\%$ at glucose levels > 75 mg/dL when compared to the readings near sea level. The labeling states that the Arkray Assure Pro test strips can be used at elevations up to 10,000 feet above sea level.

Hematocrit Study

The sponsor performed hematocrit studies comparing the Assure Pro result at various hematocrits across the glucose measuring range to the Assure Pro at a normal hematocrit and to a reference analyzer. Hematocrit levels tested were 30, 37, 42, 53, and 55% and glucose levels tested were approximately 26, 52, 69, 119, 172, 335, 437, and 519 mg/dL. All of the comparisons to the reference analyzer and to a normal hematocrit showed a bias of less than ± 15 mg/dL at glucose concentrations less than 75mg/dL or less than $\pm 15\%$ at glucose concentrations ≥ 75 mg/dL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed with 106 capillary fingerstick patient samples. The distribution of gender, diabetes type, age, and education level were as follows:

Gender	Number	% of Total
Male	56	53
Female	50	47

Diabetes	Number	% of Total
Type 1	18	17
Type 2	88	83

Age Group	Number	% of Total
18 – 30	5	5
31 – 45	15	14
46 – 55	28	26
56 and older	58	55

Education Level	Number	% of Total
Some High School	4	4
High School Graduate	18	17
Some College or Technical School	53	50
4-year College Degree	18	17
Graduate Courses or Degree	13	12

An additional 37 values were obtained from capillary blood that was allowed to undergo glycolysis to lower glucose or was spiked with glucose to raise values, for a total of 143 measurements. The range of measurements was 28 – 495 mg/dL.

System accuracy results for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
22/24 (92%)	24/24 (100%)	24/24 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
78/119 (66%)	108/119 (91%)	118/119 (99%)	119/119 (100%)

b. *Matrix comparison:*

Not applicable. Only capillary whole blood samples can be used with this meter.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

The method comparison study was performed by consumers (please see section 2.a. above).

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected values for people without diabetes¹:

Fasting: <100 mg/dL

1 – 2 hours after meals < 140 mg/dL

¹Joslin Diabetes Center: Goals for Blood Glucose Control. www.joslin.org

N. Instrument Name:

Assure Pro Blood Glucose meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for each additional reading.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.

Yes X or No _____

3. Specimen Identification:

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

as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

The user is instructed to insert the code chip when the meter is turned off, and then to insert a test strip, which turns the meter on. The meter automatically detects the code number when a test strip is inserted. The user must check to see if the code number the meter displays matches the number on the test strip vial. If the number matches, the user is instructed to begin testing. If the number does not match, the user is instructed not to test and to call customer service. No other calibration is required from the user.

6. Quality Control:

Two levels of control are supplied with the device. Users are instructed to run controls when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, when they suspect the meter or strips are not working correctly, if test results appear to be abnormally high or low, or are not consistent with the patient's symptoms, if the meter is dropped, to check their technique, if the test strip bottle had been left open or stored outside its recommended temperature range, or when the meter has been stored outside its recommended temperature range, and each time the batteries are changed.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

The sponsor performed a readability assessment of the labeling and states that the user manual, strip insert, and control insert are at an eighth grade reading level or below. Note: the strip insert was determined to be at a reading level of 8.5 when the technical section targeting professional users was included. When this section was not included, the reading level drops to 7.4.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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