

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

A. 510(k) Number:

k082965

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative glucose oxidase

E. Applicant:

Alliance International Co., Ltd

F. Proprietary and Established Names:

DS-A Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose

21 CFR § 862.1660, Quality Control Material, assay and unassayed

2. Classification:

Class II, Class I, reserved

3. Product code:

CGA—Glucose oxidase, Glucose

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

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

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The A-CHECK DS-A Blood Glucose Monitoring System is used with DS-A Test Strips and 3-level Controls for the measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The DS-A Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. DS-A Test Strips must be used with the A-CHECK DS-A Blood Glucose Monitoring System. Testing is done outside the body (In Vitro diagnostic use). They are 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. They are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.

The Alliance Blood Glucose 3 levels Control Solution are for use with the A-CHECK DS-A Blood Glucose Monitoring System and DS-A Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

Over the Counter (OTC)

Not for diagnosis of or screening for diabetes mellitus

Not for use on neonates

Not for use for alternative site testing

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

4. Special instrument requirements:

DS-A Blood Glucose Meter

I. Device Description:

The DS-A Blood Glucose Monitoring System consists of the DS-A Blood Glucose meter and the DS-A Draw-In Blood Glucose Test Strips. The start-up kit includes the DS-A Blood Glucose Meter with battery, lancet device and 10 lancets, DS-A Draw-In Glucose Test Strips with code card, User’s Manual, Quick Reference Guide, Diary for Self-Monitoring and a mid-level Quality Control solution.

Alliance Blood Glucose Control Solutions are three levels of controls which are used for performance checks on the Draw-In Blood Glucose Test Strips and are purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Accu-Chek Aviva System

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

k043474

3. Comparison with predicate:

Similarities		
Items	A-CHECK DS-A (Alliance International) Subject Device	Accu-Chek Aviva (Roche) Predicate Device (k043474)
Intend Use	The A-CHECK DS-A Blood Glucose Monitoring System is used with the A-CHECK DS-A Draw-In Blood Glucose Test Strips and 3-level Controls for the measurement of glucose in whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over-the-counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.	The ACCU-CHEK Aviva system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring blood glucose in the home or health care facility. The device is intended for professional use and over-the-counter sale. Professionals may use the test strip to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

Meter Dimension	94.5mm x 56mm x 27.5mm	94mm x 53mm x 22.86mm
Sample Volume	1 uL	0.6uL
Measuring Time	6 seconds	5 seconds
Detecting Range	20 ~ 600 mg/dL	10~ 600 mg/dL
HCT Range	30 ~ 55 mg/dL	20-70 mg/dL
Battery Power	One 3V Lithium CR 2032 battery	One 3V lithium coin cell battery
Meter Check	Resistor (Code Card)	Resistor (Code Key)
Data Recall	By button	By button
Button Design	Two buttons	Two buttons
Strip Dimension	35mm x 7mm x 0.35mm	37mm x 9mm x 0.35mm

Differences		
Items	A-CHECK DS-A (Alliance International) Subject Device (k082965)	Accu-Chek Aviva (Roche) Predicate Device (k043474)
Test Principle	GOD Electrochemical biosensor with carbon electrodes	GDH Electrochemical
Meter Weight	56 g	60 g
Memory Storage	360 test results	500 blood glucose results
Meter Coding	Code Card	Code Key
Operating Temperature	14 to 40 °C	6 to 44 °C
Strip Storage Temperature	4 to 32 °C	2 to 32 °C
Limitations	Not for use with venous serum or plasma samples.	For use with venous serum or plasma or capillary whole blood

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

CLSI EP 7A2: Interference Testing in Clinical Chemistry

ISO 15197:2003, *In Vitro* Diagnostic Test Systems—Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus.

IEC/EN 61010-1, Medical electrical equipment Part 1. General requirements for safety, 2001.

L. Test Principle:

The DS-A Draw-In Blood Glucose Test Strips use the reaction of glucose oxidase (GOD) with capillary whole blood glucose to form gluconic acid. This, in turn reacts with potassium ferricyanide on the strips to form ferricyanide. During this reaction, electrons are released which generate a current proportional to the concentration of glucose present in the sample.

The DS-A Blood Glucose Meter uses amperometric biosensor technology to convert the electronic signal to concentration which is displayed on the meter. The meter is calibrated by inserting a lot specific calibration strip into the meter prior to starting a new box of test strips. This is provided in each box of test strips.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Repeatability studies were conducted using venous blood samples with target concentrations of 40 mg/dL, 80 mg/dL, 120 mg/dL 200 mg/dL and 300 mg/dL. Concentrations were confirmed on the Yellow Springs analyzer (YSI). Within-run precision was determined by analyzing each sample 40 times on each of 3 lots of strips. The summary of all lots is below

Within-run Precision (Repeatability)

	40 mg/dL			80 mg/dL			120 mg/dL			200 mg/dL			300 mg/dL		
Mean	41	42	42	86	92	87	132	128	140	209	212	211	323	330	332
SD	2.5	2.5	2.6	3.8	3.6	4.2	6.4	5.5	4.0	4.7	5.2	4.9	7.0	8.1	9.1
%CV	6.1	5.7	6.2	4.4	3.9	4.8	4.8	4.3	2.8	2.3	2.4	2.3	2.2	2.4	2.7

Day-to-day precision studies were conducted using quality control material at 3 levels, 50 mg/dL, 120 mg/dL and 340 mg/dL, three lots of test strips and 12 meters. The testing was performed for 10 days and consisted of four replicates per day per strip lot. Control values were verified with the YSI Glucose Analyzer.

	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
AVG. (mg/dL)	53	53	52	135	134	136	340	340	340
S.D. (mg/dL)	2.3	2.1	2.2	5.7	4.6	5.4	11.5	10.8	13.9
C.V.%	4.3%	3.9%	4.2%	4.2%	3.4%	4.0%	3.4%	3.2%	4.1%

b. *Linearity/assay reportable range:*

Five venous whole blood samples were spiked with glucose to cover the measuring range of 20-600 mg/dL, and evaluated 20 times per sample on the DSA Blood Glucose meter and the YSI analyzer. Values ranged from 21-590 mg/dL. Each sample was analyzed on 5 A-Check DS-A meters with 2 lots of test strips. Linear regressions for each strip lot compared to the YSI are below:

Lot	Slope	Intercept	r	R ²
1	1.02	-2.1 mg/dL	0.996	0.993
2	1.01	2.5 mg/dL	0.997	0.994

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

There are three levels of Quality Control material available for separate purchase. They cover the low, middle and high glucose range. The mid-range control is included with each test kit.

Traceability

- 1) Traceability: The DS-A-CHECK meter is compared to the YSI 2300 Glucose Analyzer in the accuracy studies below. The YSI is calibrated with NIST (SRM) 917a reference material. Quality control material is gravimetrically prepared and assayed on the DS-A-Check meters in multiple runs to establish ranges. Control ranges are included on each vial of test strips.

Stability

- 1) Accelerated and real-time temperature and humidity studies for the DS-A Draw-In Test Strips were conducted to determine closed and open vial test strip stability and to verify performance of the meter and strips at temperatures of 0° C-40° C. Real time studies were conducted for 19 months. Closed vial stability is 18 months at 24°C ± 3°C and 60% ± 10% relative humidity. Open vial strip stability is 90 days at 4-32° C at 80% relative humidity. Recommended operating temperatures are 14° C-40° C.
- 2) Alliance Blood Glucose Control Solutions stability studies were conducted in real time. Closed vial stability at 23°C to 27°C is 18 months. Open vial stability studies were performed at 20° C, 25° C and 30° C. Open vial stability for 20° C-30° C is 90 days.

Calibration

The meter is factory calibrated but each vial of test strips has a calibration card containing the calibration coefficients for each lot of test strips. The Operator's Manual instructs the user to load the calibration card for each test vial prior to using

the strips in a new vial. The lot number displayed on the meter after loading the calibration card must match the lot number on the strip vial. If there is no match, an error message is generated and no glucose result is displayed.

d. Detection limit:

The detection limit is 20 mg/dL as described in section M.1.b. above.

e. Analytical specificity:

Endogenous and Exogenous Interference

Endogenous and exogenous substances were analyzed at two concentrations of glucose and interferent according to CLSI EP 7. Each concentration of interferent was added to whole blood samples whose glucose concentrations had been adjusted to between 100-150 mg/dL, and 200-250 mg/dL as measured on the YSI 2300 analyzer. The sponsor defined no significant interference as less than 10% interference when compared to the control pools with no interferents added. Results are summarized below.

Summary of Interferences

#	Substance	Exogenous Substance			Elevated Challenge	Significant Interference Pos/Neg
		Therapeutic Concentration	Test Concentration (Low)	Significant Interference Yes/No		
1	Acetaminophen	1-2 mg/dL	2mg/dL	no	20mg/dL	no
2	Ascorbic Acid	0.8 – 1.2 mg/dL	1.2mg/dL	yes	3mg/dL	yes
3	Dopamine	N.A.	1.25 mg/dL	yes	30mg/dL	yes
4	Ibuprofen	0.5 – 4.2 mg/dL	4.4mg/dL	no	40mg/dL	no
5	L-Dopa	N.A.	10mg/dL	yes	20 mg/dL	yes
6	Tetracycline	0.4 mg/dL	0.4mg/dL	no	0.4mg/dL	no
7	Tolbutamide	5.3 - 10 mg/dL	10mg/dL	no	100mg/dL	no

#	Substance	Endogenous Substance			Elevated Challenge	Significant Interference Yes/No
		Normal Concentration	Test Concentration (Low)	Significant Interference Yes/No		
1	Cholesterol	250 mg/dL	250mg/dL	no	500mg/dL	no
2	Creatinine	1.5 mg/dL	1.5mg/dL	no	30mg/dL	no
3	Uric Acid	7 mg/dL	7mg/dL	yes	20mg/dL	yes

Hematocrit

Six whole blood samples with hematocrits ranging from 30% - 55% were tested at four different glucose concentrations of approximately 50 mg/dL to 500 mg/dL against the YSI. The percent differences of the DS-A glucose results at each hematocrit level were calculated against the YSI glucose results at 40% hematocrit. The sponsor demonstrated that for each level of hematocrit there was $\leq 12\%$ difference across the entire glucose range. A caution about using samples with $< 30\%$ or $> 55\%$ is stated in the labeling.

Altitude Studies

Altitude studies were performed using five whole blood samples with glucose concentrations from 52-498 mg/dL as determined on the YSI 2300. Each sample was tested in duplicate on six meters and 1 lot of test strips at 6 altitudes. Values were compared to the YSI 2300 (see chart below) The sponsor demonstrated a $< 16\%$ CV for all samples across all lots on the DS-A-CHECK for glucose concentrations between Sea level.- 8,563 ft. Summarized results are below:

YSI	52 mg/dL	121 mg/dL	202 mg/dL	354 mg/dL	498 mg/dL
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Test Altitudes/Test Conc.	50mg/dL	120mg/dL	200mg/dL	350mg/dL	500mg/dL
Sea Level	57	127	207	360	507
775 meters/2542.6 ft.	57	125	208	362	506
1460 meters/4790 ft.	57	126	209	363	508
1900 meters/6528.8 ft.	56	126	208	361	509
2310 meters/7578.7 ft.	56	125	209	362	506
2610meters/8562.9 ft.	49	120	200	350	499
Mean	55	125	207	360	506
SD	2.87	2.27	3.13	4.42	3.24
CV%	5.2%	1.8%	1.5%	1.2%	0.6%

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

178 capillary whole blood samples were collected from test subjects and analyzed in singlicate by a laboratory professional and were analyzed on the DS-A Check meter and the YSI 2300. To obtain the very high and very low levels, 8 samples were collected immediately after the individual finished a meal and 8 samples were stored overnight. Glucose concentrations ranged from 31-541 mg/dL.

Regression for the DS-A glucose system and the YSI was $y=1.0032x + 4.5469$, $r^2=0.9938$. The study met the ISO 15197 standard where ninety-five percent (95%) of the individual glucose results fall within ± 15 mg/dL of the reference results at glucose concentrations <75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. The data summary for capillary samples tested by professionals is shown below:

Accuracy for glucose < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 /mg/dL	Within ± 15 mg/dL
16/32 (50.0%)	25/32 (78.1%)	32/32 (100%)

Accuracy for glucose ≥ 75 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
102/146 (69.9%)	124/146 (84.9%)	136/146 (93.2%)	146/146 (100.0%)

b. *Matrix comparison:*

Not applicable. The device is for capillary fingerstick only.

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):*

A 150 sample lay user study of English speaking subjects was conducted at three

Physician’s Office Laboratories (POL). Each lay user read the User’s Guide in English and collected and tested a fingerstick sample on themselves. A laboratory professional also collected a fingerstick from the subjects to analyze on the YSI and a venous blood sample to check the hematocrit levels. Fingerstick samples ranged from 49-424 mg/dL. Hematocrits ranged from 35-55 %. Three lots of test strips and one meter was used by the lay users. The regression for the lay user results compared to the YSI was $y=0.954x + 0.3382$, $r^2 = 0.996$. The study met the ISO 15197 standard where ninety-five percent (95%) of the individual glucose results shall fall within ± 15 mg/dL of the reference results at glucose concentrations <75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. The breakdown of lay user results following ISO 15197 is shown below:

Accuracy for glucose < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
15/18 (83.3%)	18/18 (100%)	18/18 (100%)

Accuracy for glucose ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
83/132 (62.9%)	129/132 (98%)	131/132 (99.2%)	132/132 (100%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care, Vol. 27, Supplement 1, p. S9.)

Time	Range (mg/dL)	Range (mmol/L)
Fasting	70 to 100	3.9 to 6.1
Two hours after meals	less than 140	less than 7.8

N. Instrument Name:

DS-A-CHECK Blood Glucose meter

O. System Descriptions:

1. Modes of Operation:

The DS-A-CHECK blood glucose meter uses single test glucose strips. Each test strip must be replaced with a new strip for additional readings.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device? Yes _____ or No X

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission? Yes _____ or No X

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. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

Strip lot-specific calibration is accomplished by inserting a calibration card, which comes with each vial of DS-A-Draw-In test strips, into the DS-A-CHECK meter. The meter records the calibration coefficients and the strip lot number. When the test strip is inserted into the meter, the meter detects the lot number and matches it to the information from the calibration card.

6. Quality Control:

The sponsor has three levels of controls which are purchased separately. The mid range control is included with the kit. When a test strip is inserted into the meter, a control can be analyzed. An acceptable range for each control level is printed on the individual control vial labels. The user is referred to a troubleshooting section at the end of the control test instructions of the owner's manual to identify possible reasons control results fall outside these ranges and is instructed to contact Customer Assistance or their health care provider.

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

An ease of use study was conducted with 150 lay users who collected and analyzed their own fingerstick samples using only the labeling for guidance. See section M. 3. c for their results compared to a reference method. They were also given a survey of 12 questions to evaluate their comprehension of the written materials. On a scale of 1-5 with 5 being the easiest to use or understand, the results ranged from 4.34 for the clarity of the illustrations, to 4.89 for the overall design.

In addition, the sponsor provided completed certificates and reports for Electrical Safety and EMC.

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.