II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

DEC - 7 2009

2.1. General Information Establishment

- Date Prepared: September 28, 2008
- Manufacturer: **ALLIANCE International Co., Ltd.**
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Device

- **Proprietary Name:** DS-A Blood Glucose Monitoring System
- **Common Name:** Blood Glucose Monitoring System
- **Classification Name:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II
- **Product Code:** NBW

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to ACCU-CHEK Aviva System **(k043474).**

- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, DS-A Blood Glucose Monitoring System only needs a small amount of blood. Capillary action at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds.

  The Draw-In blood glucose test strip is designed to provide an easy, accurate method for the determination of blood glucose in **fingertip capillary whole blood**. When the blood is applied to the edge of reaction zone, the blood is drawn into the reaction chamber and will display a reading on the meter. Only a small amount of blood is needed. The test strip for the quantitative measurement of blood glucose in the range is from 20-600 mg/dL (1.1-33.3 mmol/L).

- **Intended 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 is 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.

- **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to ACCU-CHEK Aviva System **(k043474).** Both of them have the same working principle and technologies. The differences are coding method, sample volume, meter dimension, weight, HCT range, and memory data number. Besides, the subject device is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger but the predicate device can test whole blood include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf. Thus the differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

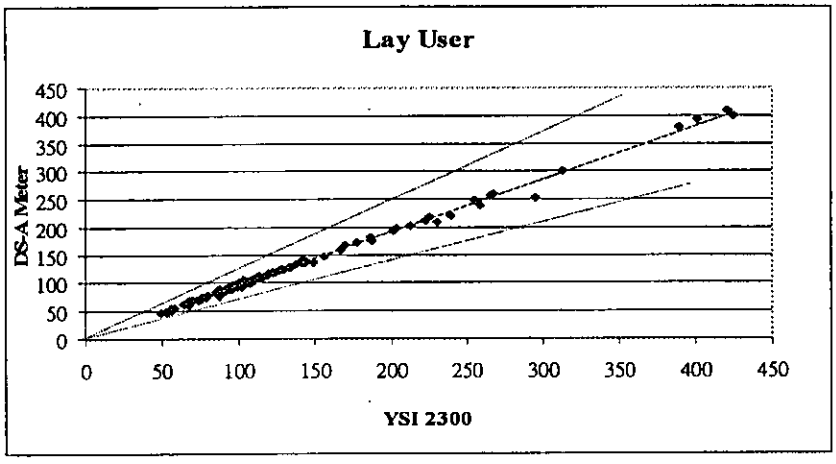
Differences		
Items	**A-CHECK DS-A (Alliance International)** Subject Device (k082965)	**Accu-Chek Aviva (Roche)** Predicate Device (k043474)
Test Principle	GOD Electrochemical biosensor with carbon electrodes	GDH Electrochemical
Meter Weight	56 g	60 g
Memory Storage	360 test results	500 blood glucose results
Meter Coding	Code Card	Code Key
Operating Temperature	14 to 40 ℃	6 to 44 ℃
Strip Storage Temperature	4 to 32 ℃	2 to 32 ℃
Limitations	A-Check Draw-In test strips are designed for use with fresh capillary whole blood sample. **Do Not** use serum or plasma samples. 1. It should not be used in Intensive Care settings or if the patient is dehydrated, hypotensive, hypoxic, in diabetic ketoacidosis, in shock, or in a hyperglycemic/hyperosmolar state. 2. Hematocrit: Variation in sample hematocrit between 30% and 55% has no significant effect on test results. Very high (above 55%) and very low (below 30%) hematocrit can cause inaccurate results. 3. Neonates: Do not use Draw-In test strips to test neonates. The performance of this system has not been validated with neonatal samples. 4. Blood concentration of Ascorbic Acid > 1.2mg/dL or Uric Acid > 7mg/dL will cause overestimation of blood glucose results. 5. Therapeutic levels of L-dopa (>10mg/dL) or Dopamine (> 30mg/dL) may result in inaccurate (elevated) glucose readings with the system. 6. Acetaminophen (<20mg/dL), Ibuprofen (<40mg/dL), Tetracycline (< 0.4mg/dL), Tolbutamide (<100mg/dL), Cholesterol (<500mg/dL), and Creatinine (<30mg/dL) may not affect the glucose meter readings.	1. The injection or infusion of solution containing galactose or maltose (present in some human immunoglobulin preparations) may cause overestimation of blood glucose results. 2. Blood concentrations galactose> 10mg/dL or maltose > 13 mg/dL will cause overestimation of blood glucose results. 3. Do not use during a xylose absorption test. 4. Lipemic samples in excess of 4800 mg/dL may produce elevated results. 5. In situations of decreased peripheral blood flow, fingerstick blood testing may not be appropriate as it may not reflect the true physiological state. Examples would include, but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperglycemic hyperosmolar nonketotic state, hypotension, chock severe congestive heart failure, or peripheral vascular disease. 6. Blood glucose determination with venous blood must be performed within 30 minutes of ample collection. 7. For best results with venous blood, the following anticoagulants/preservation is recommended: heparin or EDTA. Serum separator tubes are acceptable if whole blood is used immediately, lodoacetate or fluoride-containing anticoagulants are not recommended. 8. Refrigerated samples should be brought to room temperature slowly prior to testing.

- **Synopsis of Test Methods and Results**

Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

For Home Users

The table below was based on a study done with 150 patients to see how well the A-Check DS-A Blood Glucose Monitoring System compared to the YSI 2300.



Results for glucose concentration < 75mg/dL (4.2 mmol/L)

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

Results for glucose concentration ≥ 75mg/dL (4.2 mmol/L)

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

A-CHECK DS-A Meter vs. YSI analyzer			
n	Slope	Intercept	R^2
150	0.954	0.3382	0.996

Precision (Repeatability Precision)

To compare the precision of Draw-In series test strips and the YSI 2300 STAT Plus™ glucose analyzer, oxygenated Heparin-venous blood, properly reconstituted with exogenous glucose to a final concentration of 40, 80, 120, 200, and 300 mg/dL. 40 tests of Draw-In series test strips were performed with each glucose concentration. The results obtained were as follows:

Glucose Concentrations(mg/dL)	40	80	120	200	300
Number of Tests	40	40	40	40	40
AVG. (mg/dL)	42	88	133	211	329
S.D. (mg/dL)	2.5	4.8	7.5	5.1	8.8
C.V.%	5.9%	4.4%	4.0%	2.3%	2.5%

Linearity

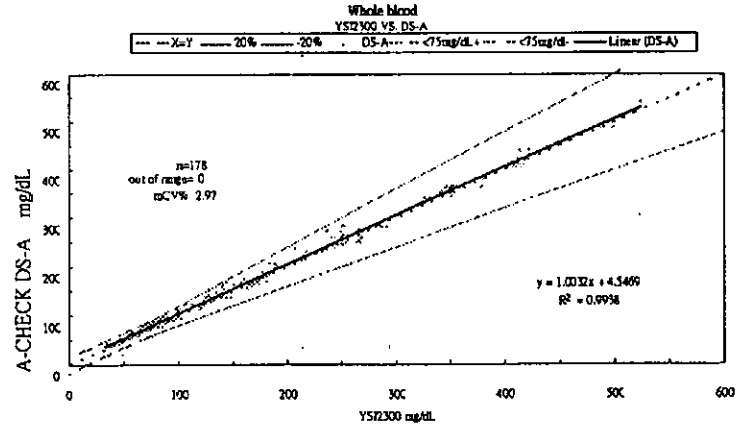
A-CHECK DS-A Blood Glucose Meter comparison with YSI 2300: 2 lots of Draw-In test strips were tested to assess the accuracy of the A-CHECK DS-A Blood Glucose Monitoring System by comparing to the reference method (YSI 2300) using venous whole blood concentrations between 20 and 600 mg/dL. The linear regression correlations are as follows:

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

Y= A-CHECK DS-A Blood Glucose Meter
X= YSI 2300

Accuracy

Accuracy (A-CHECK DS-A Blood Glucose Meter) comparison with YSI: 1 lot of Draw-In test strips were tested to assess the accuracy of the A-CHECK DS-A Blood Glucose Monitoring System by comparing to the reference method (YSI 2300) using whole blood concentrations. The table below was based on a study done with 178 patients getting samples by professionals to see how well the A-Check DS-A Blood Glucose Monitoring System compared to the YSI 2300. The accuracy regression correlations are as follows:



YSI2300 VS. A-CHECK DS-A (Whole Blood)

A-CHECK DS-A System accuracy results for glucose concentration < 4.2 mmol/L (< 75mg/dL)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/32 (50.0%)	25/32 (78.1%)	32/32 (100%)

A-CHECK DS-A System accuracy results for glucose concentration ≥ 4.2 mmol/L (≥ 75mg/dL)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
102/146 (69.9%)	124/146 (84.9%)	136/146 (93.2%)	146/146 (100.0%)

Lot	Slope	Intercept	r	R^2
1	1.00	4.5mg/dL	0.997	0.993

Y= A-CHECK DS-A Blood Glucose Meter
X= YSI 2300

Dr. Jen, Ke-Min
official correspondent for
ALLIANCE International Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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DEC - 7 2009

Re: k082965
Trade/Device Name: DS-A Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: CGA, NBW, JJX
Dated: November 20, 2009
Received: December 01, 2009

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): (k)082965

Device Name: ***DS-A Blood Glucose Monitoring System***

Indication For Use:

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Prescription Use _____ (21 CFR Part 801 Subpart D)

And / Or

Over the Counter Use √ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) (k)082965