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

A. 510(k) Number:

k170241

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood samples drawn from the fingertips

D. Type of Test:

Quantitative, electrochemical method, glucose dehydrogenase

E. Applicant:

All Medicus Co., Ltd.

F. Proprietary and Established Names:

GlucoDr.S Blood Glucose Monitoring System

GlucoDr.S BLE Blood Glucose Monitoring System

GlucoDr.S NFC Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW – System, Test, Blood Glucose, Over The Counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   GlucoDr.S Blood Glucose Monitoring System
   GlucoDr.S Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

   GlucoDr.S Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S Blood Glucose Monitoring System is not for use in neonates.

   GlucoDr.S Blood Glucose Test Strips are for use with GlucoDr.S™ Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

   GlucoDr.S BLE Blood Glucose Monitoring System

   GlucoDr.S BLE Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S BLE Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

   GlucoDr.S BLE Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S BLE Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S BLE Blood Glucose Test Strips are for use with GlucoDr.S BLE Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

GlucoDr.S NFC Blood Glucose Monitoring System

GlucoDr.S NFC Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. GlucoDr.S NFC Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

GlucoDr.S NFC Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoDr.S NFC Blood Glucose Monitoring System is not for use in neonates.

GlucoDr.S NFC Blood Glucose Test Strips are for use with GlucoDr.S NFC Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

3. Special conditions for use statement(s):

GlucoDr.S, GlucoDr.S BLE, and GlucoDr.S NFC Blood Glucose Monitoring Systems

- For over-the-counter use
- For single patient use only
- The GlucoDr.S Blood Glucose Monitoring System should not be used for diagnosis of or screening for diabetes mellitus.
- The GlucoDr.S Blood Glucose Monitoring System should not be used in critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state and with or without ketosis.
- Not for neonatal use
- A hematocrit that is either very high (above 65%) or very low (below 20%) can cause false test results.
- Dehydration may cause higher test results.
- The GlucoDr.S Blood Glucose Monitoring System is for *in vitro* diagnostic use.
- Only for use with fresh capillary whole blood
- The system has not been tested above 10,000 ft.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been part of glycemic control procedures. 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.

I. Device Description:

GlucoDr.S, GlucoDr.S BLE, and GlucoDr.S NFC
The GlucoDr.S, GlucoDr.S BLE, and GlucoDr.S NFC are for self-testing, single-patient home use and are the same devices except for the data transfer features. All three systems can transfer test results to a PC or to a smart device via a USB cable. The GlucoDr.S BLE additionally offers Bluetooth data transfer features and the GlucoDr.S NFC additionally offers Near Field Communication data transfer features.
Each system consists of a GlucoDr.S blood glucose meter, GlucoDr.S blood glucose test strips, GlucoDr.S control solution (Level 1 and Level 2; sold separately), lancet, reusable lancing device, USB cable (sold separately), LinkDr for PC (k130657; downloadable) or LinkDr App (downloadable), and user manual.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   GlucoDr. Auto Blood Glucose Monitoring System

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

   K083628

3. Comparison with predicate:

Item	Candidate Device: GlucoDr.S/ GlucoDr.SBLE/ GlucoDr.S NFC Blood Glucose Monitoring Systems	Predicate Device: GlucoDr. Auto Blood Glucose Monitoring System (k083628)
Intended use	Intended to be used for the quantitative measurement of glucose as an aid to monitor the effectiveness of diabetes control program.	Same
Intended use population	Single-Patient use	Single-Patient or Multi-Patient use
Sample type	Capillary whole blood drawn from fingertips	Venous, arterial, and capillary whole blood. Testing sites include fingertips, palm, upper arm, forearm, thigh, and calf.
Sample volume	0.5 µl	Same
Methodology	Glucose Dehydrogenase	Same
Test time	5 seconds	Same
Glucose test range	20 – 600 mg/dL	Same

Item	Candidate Device: GlucoDr.S/ GlucoDr.SBLE/ GlucoDr.S NFC Blood Glucose Monitoring Systems	Predicate Device: GlucoDr. Auto Blood Glucose Monitoring System (k083628)
Hematocrit	20-65%	20-60%
Maximum altitude	10,000 feet	8,202 feet
Operating Humidity	15-85%	Below 85%
Operating temperature	50-104°F	Same
Data upload	USB, Bluetooth Low Energy (BLE), and/or Near Field Communication (NFC)	USB
Control solutions	2 levels	Same

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

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved guideline – Third Edition

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition

IEC 61010-1 Edition 3.0 2010-06, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements [Including: Corrigendum 1 (2011)]

IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

L. Test Principle:

The GlucoDr.S Blood Glucose Monitoring Systems are based on measurement of electric currents caused by the reaction of glucose with the reagents on the gold electrode of the test strip. The blood sample is drawn into the test strip's reaction chamber through capillary action. Glucose in the sample reacts with glucose dehydrogenase and mediator on the test strip. This reaction creates electric currents. The consequent electric currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the GlucoDr.S Blood Glucose Meters.

M. Performance Characteristics (if/when applicable):

Performance testing was conducted using the GlucoDr.S Blood Glucose Monitoring System, which is representative of the other two blood glucose monitoring systems. There are no differences between the three systems that would affect performance.

1. Analytical performance:

a. Precision/Reproducibility:

Within-run precision was determined according to CLSI EP05-A2. Human venous blood samples from one donor were adjusted to 5 glucose levels (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Samples were tested on 10 GlucoDr.S meters with 3 lots of test strips. Each sample was tested over 1 day in 10 replicates per meter and per test strip lot, giving a total of 100 measurements per lot for a total of 300 measurements for each glucose level. Blood samples were also tested in duplicate by a comparator measurement procedure (YSI 2300 STAT Plus). Results are summarized below:

Combined lots

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	41.7	2.4	5.7
	2	41.5	2.5	6.0
	3	43.7	2.6	5.8
	Combined	42.3	2.7	6.3
51-110	1	81.4	3.2	4.0
	2	81.0	2.8	3.5
	3	83.5	3.0	3.6
	Combined	81.9	3.2	3.9
111-150	1	112.1	4.4	3.9
	2	112.5	3.9	3.5
	3	141.9	3.7	3.2
	Combined	113	4.2	3.7
151-250	1	182.2	5.6	3.1
	2	187.1	7.0	3.7
	3	186.1	5.1	2.8
	Combined	185	6.3	3.4
251-400	1	314.9	10.9	3.4
	2	321.8	11.4	3.6
	3	307.9	8.4	2.7
	Combined	315	11.7	3.7

Intermediate precision was evaluated using 5 levels of glucose control solution (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Each control level was analyzed on 10 meters using 3 lots of test strips each day for a total of 10 days, giving a total of 100 measurements per lot for a total of 300

measurements for each glucose level. Controls were also tested in duplicate by a comparator measurement procedure (YSI 2300 STAT Plus). Results are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	38.8	1.3	3.0
	2	37.6	1.0	2.7
	3	39.1	1.4	4.2
	Combined	38.0	1.4	3.7
51-110	1	81.1	1.6	1.3
	2	80.4	1.5	0.8
	3	81.0	2.1	2.6
	Combined	81.0	1.8	2.2
111-150	1	120	2.1	0.8
	2	117	2.6	1.7
	3	119	2.6	2.4
	Combined	119	2.6	2.2
151-250	1	198.3	3.5	1.5
	2	199.1	3.0	0.7
	3	199.8	3.7	1.1
	Combined	199	3.5	1.7
251-400	1	354	7.7	1.1
	2	354	7.4	1.2
	3	352	6.8	1.3
	Combined	353	7.4	2.1

b. *Linearity/assay reportable range:*

Linearity testing was performed according to CLSI EP6-A. A low glucose human venous blood sample (aged to deplete glucose) and a high glucose venous blood sample (spiked with glucose) were mixed to create 15 glucose levels: 15 mg/dL, 20 mg/dL, 43 mg/dL, 61 mg/dL, 78 mg/dL, 136 mg/dL, 194 mg/dL, 252 mg/dL, 310 mg/dL, 368 mg/dL, 426 mg/dL, 484 mg/dL, 542 mg/dL, 600 mg/dL, and 650 mg/dL. Each sample was measured in 5 replicates with 3 GlucoDr.S meters and 3 test strip lots and the values compared to a comparator method (YSI 2300 STAT Plus). Results from the regression analysis are as follows:

Test Strip Lot	Slope	Y-intercept	R^2
1	0.97622	1.23230	0.99951
2	0.99754	-3.82987	0.99880
3	0.98965	-2.19569	0.99827
Combined	0.98780	-1.59775	0.99914

The reportable range for glucose measurements is 20-600 mg/dL. If a sample glucose level is below 20 mg/dL, 'LO' will be displayed on the glucose meter. If a sample glucose level is above 600 mg/dL, 'HI' will be displayed on the glucose meter.

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

Traceability

The GlucoDr.S Blood Glucose Monitoring Systems are traceable to NIST SRM 917c glucose reference material.

Test Strip Stability

Test strip stability was assessed using accelerated and real-time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a shelf life stability of 19 months and an open vial stability of 4 months at the recommended storage conditions of 34°F to 90°F (1°C to 32°C) and relative humidity of 15% to 85%.

d. *Detection limit:*

The reportable range for the GlucoDr.S Blood Glucose Monitoring Systems is 20 – 600 mg/dL. See the linearity study above (M.1.b.).

e. *Analytical specificity:*

Interference studies were performed in accordance with CLSI EP07-A2. Endogenous or exogenous substances, each at two concentrations (normal/therapeutic and high/toxic), were added to venous whole blood samples and adjusted to 3 glucose concentrations (70 mg/dL, 130 mg/dL, and 260 mg/dL). Each test sample containing interferent was measured using 10 GlucoDr.S meters with 3 lots of test strips. The difference between each test sample (measured with the candidate device) and paired control sample (measured with YSI) was calculated for each substance. The table below shows the highest levels of substance tested at which no significant interference (as defined by ± 10 mg/dL for glucose concentrations < 75 mg/dL and ± 10% for glucose concentrations ≥ 75 mg/dL) was observed:

Substance	**Highest concentration with no significant interference (mg/dL)**
Acetaminophen	20
Ascorbic acid	6
Bilirubin	25
Cholesterol	505
Creatinine	10
Dopamine	3
EDTA	200
Galactose	16
Gentisic acid	10

Substance	Highest concentration with no significant interference (mg/dL)
Glutathione	93
Hemoglobin	20,000
Heparin	7.1
Ibuprofen	50
L-DOPA	2
Maltose	5,000
Methyl-DOPA	1000
Salicyclic acid	60
Sodium (NaCl)	1015
Tolazamide	16
Tolbutamide	100
Triglycerides	3333
Uric acid	8
Xylose	11
Maltitol	0.09
Mannitol	0.09
Sorbitol	0.09
Lactitol	0.09
Xylitol	0.09
Isomalt	0.09
Hydrogenated starch hydrolysates	0.09

The sponsor has included the following in the labeling:

- If you are taking high doses of Tolazamide (> 16.0 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results.
- The increased levels of the uric acid occurring naturally in the blood (> 8.0 mg/dL) may interfere with the test, resulting in inaccurate test results. High levels of uric acid are associated with a number of drugs, particularly diuretics and salicylates (aspirin).
- Do not use during or soon after xylose absorption testing. Xylose in the blood will cause interference.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

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 performance of the GlucoDr.S Blood Glucose Monitoring System in the hands of lay users was assessed with 405 participants. The lay users ranged in age and education, with 32% male and 68% female. Each participant performed a fingerstick self-test using the product instructions. Within 5 minutes, a trained healthcare professional collected a fingerstick for measurement by the comparator method (YSI 2300 STAT Plus). Samples ranged from 39.9 – 417.5 mg/dL as measured by the comparator method (YSI). Results obtained by lay users relative to the comparator method are shown below.

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/15 (80%)	15/15 (100%)	15/15 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
292/390 (74.9%)	380/390 (97.4%)	390/390 (100%)	390/390 (100%)

Regression analysis

Slope	Y-intercept	R^2
1.0155	-2.1097	0.9849

The readability of the labeling (user manual, test strip insert, control solution insert) using Flesch-Kincaid assessment were found to be written no higher than an 8th grade reading level.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected glucose values for people without diabetes:

   Fasting, plasma glucose: 70-100 mg/dL
   Two hours after a meal, plasma glucose: < 140 mg/dL

   Reference:
   American Diabetes Association: Clinical Practice Recommendations (2017). Diabetes Care, Vol 40, Supplement 1, p. S11-S124.

N. Instrument Name:

GlucoDr.S Blood Glucose Meter
GlucoDr.S BLE Blood Glucose Meter
GlucoDr.S NFC Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ____X____ or No _____

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:

   The device is intended to be used with capillary whole blood from the fingertip. The whole blood is applied directly to the test strip, so there are no special sample storage or handling considerations.

5. Calibration:

   This is a non-coding device; therefore, no calibration is required by the user.

6. Quality Control:

   The GlucoDr.S Control Solution Level 1 and Level 2 are used to confirm that the meter and test strips are working properly. Control solutions must be purchased separately from the system.

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

1. Sample Volume Study

   To verify the test strip minimum sample volume requirement (0.5 µL), fresh venous blood was spiked with glucose to obtain concentrations of 50-65 mg/dL, 100-120 mg/dL, 200-250 mg/dL, and 425-550 mg/dL. The sample volumes of 0.40 µL, 0.45 µL, and 0.5 µL were measured using 3 GlucoDr.S glucose meters and 3 test strip lots (9 measurements per sample volume) relative to the comparator method (YSI 2300 STAT Plus) results. At sample volume 0.5 µL, all GlucoDr.S meters test results supported a minimum sample volume of 0.50 µL for the GlucoDr.S meter and that the sample detection feature functioned appropriately when the sample volume was insufficient.

2. Hematocrit Study

   The effect of different hematocrit levels on the performance of the GlucoDr.S glucose meter was evaluated using venous whole blood samples with 20%, 25%, 30%, 35%, 42%, 45%, 50%, 55%, 60%, and 65% hematocrit at glucose levels of 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, and 401-600 mg/dL. Measurements were taken using 10 GlucoDr.S glucose meters and 3 test strip lots. Results of the sample at each hematocrit level were compared to samples measured with by the established comparator method (YSI 2300 STAT Plus). The study supports the claimed hematocrit range of 20-65%.

3. Altitude Study

   To assess the effect of altitude, human venous blood samples were adjusted to 4 glucose concentrations: 30-50 mg/dL, 111-150 mg/dL, 251-400 mg/dL, and 425-550 mg/dL and tested near sea level (181 feet) and 10,020 feet above sea level using 9 GlucoDr.S™

glucose meters and 3 test strip lots. Values measured by the GlucoDr.S glucose meters were compared to the comparator method YSI 2300 STAT Plus. The results support the claim that the GlucoDr.S system can be operated at altitudes up to 10,020 ft.

4. Operating Conditions (temperature, humidity)

   The effect of temperature and relative humidity on the GlucoDr.S glucose meter was evaluated using venous blood samples adjusted to 30-50 mg/dL, 96-144 mg/dL, 280-420 mg/dL, and 425-550 mg/dL glucose. Measurements were taken under four environmental conditions (50°F/15% humidity, 50°F/85% humidity, 104°F/15% humidity, 104°F/85% humidity) in replicates of 10 with 10 GlucoDr.S glucose meters. Values measured by the GlucoDr.S glucose meters were compared to the comparator method YSI 2300 STAT Plus. The study results support the operating condition claim of 50 to 104°F (10 to 40°C) with relative humidity of 15% to 85%.

5. Infection Control and Robustness Studies

   The GlucoDr.S glucose meter is intended for single-patient use only. Disinfection efficacy studies for the GlucoDr.S glucose meter was evaluated on the external meter materials by an outside commercial laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant CaviWipes Disinfecting Towelettes (EPA Registration Number 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 1,095 cleaning and disinfections cycles designed to simulate 3 years of use using the CaviWipes Disinfecting Towelettes. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electrical Safety and EMC Testing

   The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

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.