

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

A. 510(k) Number:

k102316

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

BroadMaster Biotech Corporation

F. Proprietary and Established Names:

Glucose Shepherd Pro Blood Glucose Monitoring System,

Glucose Shepherd Blood Glucose Monitoring System,

Glucose Shepherd Pro Control Solution,

Glucose Shepherd Control Solution,

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section	Panel
Glucose Shepherd Pro Blood Glucose Monitoring System	CGA	Class II	21 CFR § 862.1345, Glucose test system, Glucose oxidase	75-Chemistry
Glucose Shepherd Blood Glucose Monitoring System	CGA, NBW (over the	Class II	21 CFR § 862.1345, Glucose test system, over the counter, Glucose	75-Chemistry

	counter)		oxidase,	
Glucose Shepherd Control Solution	JJX	Class I, reserved	21 CFR § 862.1660, Quality control material	75-Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Device Name: Glucose Shepherd Blood Glucose Monitoring System

Glucose Shepherd Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The Glucose Shepherd Blood Glucose Monitoring System consists of the Glucose Shepherd Blood Glucose meter and the Glucose Shepherd Blood Glucose test strips. The Glucose Shepherd Blood Glucose meter is used only with Glucose Shepherd Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.

The Glucose Shepherd Control Solutions are for use with the Glucose Shepherd Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Device Name: Glucose Shepherd Pro Blood Glucose Monitoring System

Glucose Shepherd Pro Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use). It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Pro Blood Glucose Monitoring System may be used for multiple patients in a professional healthcare setting. It is intended for use as an aid in monitoring the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing devices. It should not be used for the diagnosis or screening of diabetes, for the testing of neonates, or for testing of arterial blood.

The Glucose Shepherd Pro Blood Glucose Monitoring System consists of the Glucose Shepherd Pro Blood Glucose meter and the Glucose Shepherd Pro Blood Glucose test strips. The Glucose Shepherd Pro Blood Glucose meter is used only with Glucose Shepherd Pro Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.

The Glucose Shepherd Pro control solutions are for use with the Glucose Shepherd Pro Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

Not for use on critically ill patients, patients in shock, severely hypotensive individuals, dehydrated patients or individuals experiencing hyperglycaemic-hyperosmolar state, with or without ketosis.

Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Multiple user devices (Glucose Shepherd Pro Blood Glucose meter) must be disinfected between users following labeling recommendations.

Multiple patient use settings are to use disposable, single use lancing devices with the meters.

4. Special instrument requirements:

Glucose Shepherd Blood Glucose Meter

Glucose Shepherd Pro Blood Glucose Meter

I. Device Description:

The Glucose Shepherd Blood Glucose Monitoring System consists of a blood glucose meter, test strips, control solutions (Level 1, Level 2, and Level 3), lancing device, and commercially available sterilized lancets. This system utilizes an amperometric method to generate a current. The size of the current is proportional to the amount of glucose presented in the sample, providing a quantitative measure of glucose level in capillary whole blood.

The Glucose Shepherd Pro Blood Glucose Monitoring System consists of the Glucose Shepherd Pro Blood Glucose meter and the Glucose Shepherd Pro Blood Glucose test strips. Glucose Shepherd Pro Blood Glucose Monitoring System consists of a blood glucose meter, test strips, control solutions (Level 1, Level 2, and Level 3), and auto-disabling single-use lancing devices. This system utilizes an amperometric method to generate a current. The size of the current is proportional to the amount of glucose level presented in the sample, providing a quantitative measure of glucose level in

capillary whole blood.

Glucose Shepherd control solutions are red aqueous solutions which contain 0.03% to 0.30% (w/v) glucose as an active ingredient and >99.7% (w/v) of inert ingredients.

The Glucose Shepherd control solutions are available at three levels (Level 1, Level 2, and Level 3).

J. Substantial Equivalence Information:

1. Predicate device name(s):
Advocate Redi-Code Blood Glucose Monitoring System
FORA Control Solution
2. Predicate 510(k) number(s):
k072039
k093724
3. Comparison with predicate:

The Glucose Shepherd Blood Glucose Monitoring System/ The Glucose Shepherd Pro Blood Glucose Monitoring System have the following similarities and differences to the predicate device:

Items	Predicate Device	Candidate Devices	
Brand Name	Advocate Redi-Code Blood Glucose Monitoring System (k072039)	Glucose Shepherd Blood Glucose Monitoring System	Glucose Shepherd Pro Blood Glucose Monitoring System
Similarities			
Indications for Use	Intended for use in the quantitative measurement of glucose in fresh capillary whole blood from finger, palm, forearm, upper-arm, calf and thigh as an aid in monitoring the effectiveness of diabetes control program	Same	Same
Enzyme	Glucose Oxidase	Same	Same
Measurement principle	Amperometric method	Same	Same
Coding	No coding	Same	Same
Power	Two 1.5V AAA alkaline batteries	Same	Same
Test range	20 mg/dL to 600 mg/dL	Same	Same
Hematocrit	20% to 60%	Same	Same
Operating conditions	50°F to 104°F (10°C to 40°C), below 85% R.H.	Same	Same

Items	Predicate Device	Candidate Devices	
Brand Name	Advocate Redi-Code Blood Glucose Monitoring System (k072039)	Glucose Shepherd Blood Glucose Monitoring System	Glucose Shepherd Pro Blood Glucose Monitoring System
Similarities			
Strip storage conditions	39.2°F to 104°F (4°C to 40°C), below 85% R.H.	Same	Same
PC link	available	Same	Same
Differences			
Weight	69.87g	53g	
Dimension	96mm (L) x 20mm (W) x 45mm (H)	64mm (L) x 95mm (W) x 29mm (H)	
Test time	7 seconds	5 seconds	
Test volume	0.7 µL	1.1 µL	
Memory	450 test results with day and time	400 test results with optional before/after meal flags, and with day and time	
Glucose units	Either mg/dL or mmol/L	mg/dL	
Alarms	None	Six	
Pre-meal and post-meal flags	None	Yes	
Items	Predicate Device	Candidate Devices	
Brand Name	FORA Glucose Control Solution (k093724)	Glucose Shepherd control solution	Glucose Shepherd Pro control solution
Similarities			
Indications for Use	As a quality control check to verify the accuracy of blood glucose test results	Same	Same
Analyte	d-glucose	Same	Same
Matrix	Aqueous	Same	Same
Target Ranges			
Number of Levels	3 Level 1: 64-92 mg/dL Level 2: 96-144 mg/dL Level 3: 280-420 mg/dL	Same	Same

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

CEN 13640 Stability Testing of In Vitro Diagnostic Reagents

CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline

IEC 60601-1-4, Medical Electrical Equipment, Part 1: General Requirements for Safety, 4. Collateral Standard: Programmable Electrical Medical Systems

IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

IEC 61010-2-010 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials

IEC 61326-1 Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 1: General requirements

IEC 61326-2-6 Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

ISO 14971 Application of risk management to medical devices

ISO 15197 In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

L. Test Principle:

Glucose Shepherd Blood Glucose Monitoring System and Glucose Shepherd Pro Blood Glucose Monitoring System use an electrochemical method. It is based on the quantitative measurement of glucose in whole blood using an amperometric method, which detects the current produced from glucose oxidation. Glucose in the sample mixes with specific chemicals on the test strip producing a small amount of electrical current. The meter measures the current, as well as other important parameters, such as ambient temperature, and displays the corresponding blood glucose level in the sample. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Since the two Glucose Shepherd blood glucose monitoring systems are identical, only one set of precision studies were provided for both the systems.

The repeatability study was performed by one operator using heparinized anti-coagulated whole blood (hematocrit ranged from 35% to 50%) at five different glucose concentrations. The final glucose concentrations for the blood samples were confirmed by YSI 2300. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strips lots and four meters with one test strip lot). Ten measurements were obtained per meter and test strip lot, and glucose concentration (N=100 per concentration level). The results are summarized below:

Repeatability

Range (mg/dL)	YSI (mg/dL)	Test Strip Lot #	Mean (mg/dL)	SD	CV%
30-50 mg/dL	44.4	1	40.4	1.91	4.71
		2	40.6	2.01	4.96
		3	41.2	1.93	4.69
		combined	40.8	1.96	4.80
51-110 mg/dL	75.8	1	87.0	4.06	4.66
		2	84.9	4.17	4.91
		3	87.8	3.89	4.43
		combined	86.7	4.16	4.80
111-150 mg/dL	136	1	144.7	4.09	2.83
		2	142.5	4.40	3.09
		3	144.7	3.50	2.42
		combined	144.0	4.06	2.82
151-250 mg/dL	228	1	246.1	3.98	1.62
		2	245.4	4.50	1.83
		3	245.8	3.69	1.50
		combined	245.8	4.00	1.63
251-400 mg/dL	376	1	349.5	9.03	2.58
		2	354.6	8.90	2.51
		3	358.9	9.45	2.63
		combined	354.8	9.88	2.79

Intermediate precision studies were performed by one operator using three levels of control solutions. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strip lots and four meters with one test strip lot) for ten days (N=100 per concentration level).

Intermediate Precision

Control solution	Test Strip Lot #	Mean (mg/dL)	SD	CV%
64-92 mg/dL	1	66.7	1.41	2.12
	2	66.6	1.74	2.61
	3	67.1	1.73	2.57
	Combined	66.8	1.64	2.46
96-144 mg/dL	1	126.7	6.28	4.96
	2	120.9	4.75	3.93
	3	127.4	5.54	4.35
	Combined	125.2	6.21	4.96
280-420 mg/dL	1	306.1	9.88	3.23
	2	307.8	9.63	3.13
	3	309.1	9.64	3.12
	Combined	307.8	9.69	4.96

b. *Linearity/assay reportable range:*

Linearity study was designed based on CLSI EP6-A guideline.

Since the two Glucose Shepherd blood glucose monitoring systems are identical, only one linearity study was provided for both the systems.

Nine heparinized venous blood samples spiked with dextrose that covered the range from 20-600 mg/dL (hematocrit 45%). Glucose concentrations were confirmed by the YSI-2300. One operator performed the study using one calibrated meter and one vial of test strips from one lot in quadruplicate (N=36 per test strip lot). The results are summarized below:

Compared to YSI	Slope	Intercept	R ²
Replicate 1	0.9673	6.0271	0.9992
Replicate 2	0.9616	8.4738	0.9984
Replicate 3	0.9409	12.436	0.9957
Replicate 4	0.9551	12.572	0.9972

The measurement range of the Glucose Shepherd Blood Glucose Monitoring Systems is 20 to 600 mg/dL.

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

Since the two Glucose Shepherd blood glucose monitoring systems are identical, only one set of traceability, value assignment and stability studies were provided for both the systems.

Glucose Shepherd Control Solutions:

Traceability and value assignment - The Glucose Shepherd control solutions are traceable to the N.I.S.T SRM 917c and the YSI-2300 analyzer. Value assignment was performed with 10 Glucose Shepherd blood glucose meters using 10 strips from six randomly selected vials of Glucose Shepherd blood glucose test strips from the same lot and three levels of control solutions. The mean, standard deviation and CV are calculated for each new lot of control material. If the three CVs are <5%, then the control range for each strip lot is calculated as mean $\pm$ 20% (for mean value $\geq$ 75 mg/dL) and mean $\pm$ 15 mg/dL (for mean value <75 mg/dL). If the CV is $\geq$ 5%, the product is judged defective and discarded.

Stability - The Glucose Shepherd control solutions are identical to FORA control solutions first commercialized under k041107, and more recently under k093724. The Glucose Shepherd control solutions are manufactured and labeled by the manufacturer. The stability study results provided were from the k041107.

Open vial control stability was tested at three control levels on two lots. Based on these studies, open vial stability is 90 days when stored tightly closed between 35°F and 86°F (2°C and 30°C). Unopened vial control stability was tested in real time at three control levels on three lots. Unopened

control solutions were tested under identical conditions as the opened control solutions. The unopened control solutions have a 24 month shelf life when stored between 35°F and 86°F (2°C and 30°C). Stability studies protocol and acceptance criteria for open and unopened vials were provided and found to be adequate.

Glucose Shepherd Test Strips:

Stability - Real time stability was performed for Glucose Shepherd test strips to assess the shelf-life and open-vial stability of the test strips. Stability studies protocol and acceptance criteria were provided and found to be adequate. The sponsor claimed that the unopened test strips have a 24 month shelf-life and are stable for 3 months after opening when stored at temperatures between 39.2°F to 104°F (4°C to 40°C) at ≤ 85% R.H.

This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b).

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline.

Since the two Glucose Shepherd Blood Glucose Monitoring Systems are identical, only one set of interference studies were provided for both systems.

Eighteen potential endogenous and exogenous interfering substances were evaluated by spiking heparinized venous blood with two levels of glucose concentrations within the ranges 80 - 120 mg/dL and 200 -300 mg/dL. The glucose samples were spiked with the potentially interfering compounds and tested on two meters using one test strip lot. Several concentrations of the interfering substances were tested as shown in the table below. Non interfering substances were tested at toxic level concentrations or 10 times the highest therapeutic concentrations as recommended in CLSI EP7-A2 guidance. The sugars with unknown blood concentration were tested at several concentrations up to 100 mg/dL (galactose and xylose) or 1000 mg/dL (maltose). If the blood concentration of the substance is not known, the concentration tested was three times the therapeutic dose distributed in 5L of blood. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. Significant interference is defined by the sponsor as a bias $\geq 10\%$ of the test samples from the control group.

The sponsor claims no significant interference (< 10% difference) for the substances and concentrations shown in the table below:

Interferent	Concentration tested (mg/dL)
Salicylate	60.0
Galactose	100.0
Maltose	1000.0
Xylose	100.0
Cholesterol	500.0
Creatinine	15.0
Triglycerides	2000.0
Methyl-Dopa	2.5
Bilirubin	20.0
Hemoglobin	500.0

Interference was observed with the substances at and above the interfering concentrations listed below:

Interferent	Interfering Concentration (mg/dL)	Concentrations tested (mg/dL)
Acetaminophen	12.5	3.6, 12.5, 25.0, 50.0
Dopamine	3.0	1.5, 3.0, 6.5, 13.0
Levo-Dopa	4.0	1.0, 2.0, 3.0, 4.0, 12.0, 15.0, 20.0
Tolbutamide	150	7.2, 42.7, 80.0, 150.0
Gentisic acid	25.0	12.5, 25.0, 37.5, 50.0
Tolazamide	15.0	3.25, 7.5, 15.0, 30.0
Ascorbic acid	7.5	3.75, 5.83, 7.5, 15.0
Uric Acid	20.0	10.0, 15.0, 20.0, 25.2
Ibuprophen	50.0	2.0, 20.0, 40.0, 50.0
Mannose	250.0	50.0, 100.0, 250.0, 500.0

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy Study using the Glucose Shepherd Pro Blood Glucose Monitoring System: The study was performed by healthcare professional at three sites over 10 days using heparinized venous blood samples from 114 patients. In addition, 3 venous samples were altered for blood glucose concentration less than 40 mg/dL and 3 venous samples were altered for blood glucose concentration greater than 400 mg/dL. The samples were tested using three lots of Glucose Shepherd Pro test strips and two Glucose Shepherd Pro meters. Distribution of glucose concentrations across the measuring range

was: 6 samples between 20 to 50 mg/dL, 18 samples between 50 to 80 mg/dL, 24 samples between 80 to 120 mg/dL, 36 samples between 120 to 200 mg/dL, 18 samples between 201 to 300 mg/dL, 12 samples between 301 to 400 mg/dL and 6 samples between 400 to 600 mg/dL. All results were compared to the YSI. The studies met ISO 15197 accuracy criteria, e.g. 95% of glucose results < 75 mg/dL were within ± 15 mg/dL of the reference method, and for samples ≥ 75 mg/dL, 95% of results were within $\pm 20\%$ of the reference method. Results are summarized below:

Regression Analysis Healthcare Venous Blood vs YSI

Test Strip	Meter	Slope	Intercept	R ²
Lot 1	1	0.963	3.127	0.988
	2	0.966	5.74	0.987
Lot 2	1	0.968	3.930	0.986
	2	0.967	4.84	0.987
Lot 3	1	0.961	4.617	0.986
	2	0.963	4.708	0.986

Healthcare Professional Venous Blood vs YSI < 75 mg/dL

Test Strip	Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	1	6/15(40%)	11/15(73%)	15/15(100%)
	2	9/15(60%)	14/15(93%)	15/15(100%)
Lot 2	1	13/15(87%)	15/15(100%)	15/15(100%)
	2	8/15(53%)	14/15(93%)	15/15(100%)
Lot 3	1	11/15(73%)	14/15(93%)	15/15(100%)
	2	10/15(67%)	14/15(93%)	15/15(100%)

Healthcare Professional Venous Blood vs YSI ≥ 75 mg/dL

Test Strip	Meter	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	1	43/105(41%)	84/105(80%)	99/105(94%)	105/105(100%)
	2	46/105(44%)	89/105(85%)	99/105(94%)	105/105(100%)
Lot 2	1	41/105(39%)	86/105(82%)	101/105(96%)	105/105(100%)
	2	35/105(33%)	86/105(82%)	101/105(96%)	105/105(100%)
Lot 3	1	49/105(47%)	85/105(81%)	103/105(98%)	105/105(100%)
	2	57/105(54%)	92/105(88%)	98/105(93%)	105/105(100%)

The Method Comparison study was performed by lay user and healthcare professional at three sites over 10 days using fresh finger stick capillary blood samples. Ninety nine patients participated in the study. Venous blood samples were collected in heparin tubes. Labeling was provided only in English and users followed it to perform testing. The samples were tested using three lots of Glucose Shepherd test strips. Distribution of glucose concentrations across the measuring range was: 5 samples between 20 to 50 mg/dL, 15 samples between 50 to 80 mg/dL, 20 samples between 80 to 120 mg/dL, 30 samples between 120 to 200 mg/dL, 15 samples between 201 to 300 mg/dL, 10 samples between 301 to 400 mg/dL and 4 samples between

400 to 600 mg/dL. All results were compared to the YSI. The studies met ISO 15197 accuracy criteria, e.g. 95% of glucose results < 75 mg/dL were within ± 15 mg/dL of the reference method, and for samples ≥ 75 mg/dL, 95% of results were within $\pm 20\%$ of the reference method. Results are summarized below:

Regression Analysis Healthcare Professional Fingerstick vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	1.000	- 0.820	0.977
Lot 2	1.034	- 4.110	0.979
Lot 3	1.019	- 3.825	0.975

Healthcare Professional Fingerstick vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	10/13(77%)	13/13(100%)	13/13(100%)
Lot 2	9/13(69%)	13/13(100%)	13/13(100%)
Lot 3	12/13(92%)	13/13(100%)	13/13(100%)

Healthcare Professional Fingerstick vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	39/86(45%)	57/86(66%)	77/86(90%)	85/86(99%)
Lot 2	40/86(47%)	64/86(74%)	83/86(97%)	86/86(100%)
Lot 3	39/86(45%)	65/86(76%)	78/86(91%)	86/86(100%)

Regression Analysis Lay User Fingerstick vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.969	+ 2.343	0.990
Lot 2	0.994	- 0.173	0.991
Lot 3	1.001	+ 0.327	0.983

Lay User Fingerstick vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	7/13(54%)	13/13(100%)	13/13(100%)
Lot 2	9/13(69%)	11/13(85%)	13/13(100%)
Lot 3	9/13(69%)	11/13(85%)	13/13(100%)

Lay User Fingerstick vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	44/86(51%)	75/86(87%)	83/86(97%)	86/86(100%)
Lot 2	48/86(56%)	75/86(87%)	85/86(99%)	86/86(100%)
Lot 3	40/86(47%)	66/86(77%)	80/86(93%)	85/86(99%)

Alternative site testing for the palm, the forearm, the upper arm, the calf and the thigh was performed by lay users and healthcare providers. The study was performed at three sites over 10 days using capillary blood samples while the

participants were in steady-state. Ninety nine patients participated in the study. Venous blood samples were collected in heparin tubes. Labeling was provided only in English and users followed it to perform testing. The samples were tested using three lots of Glucose Shepherd test strips. Distribution of glucose concentrations across the measuring range was: 5 samples between 20 to 50 mg/dL, 15 samples between 50 to 80 mg/dL, 20 samples between 80 to 120 mg/dL, 30 samples between 120 to 200 mg/dL, 15 samples between 201 to 300 mg/dL, 10 samples between 301 to 400 mg/dL and 4 samples between 400 to 600 mg/dL. All results were compared to the YSI. The studies met ISO 15197 accuracy criteria, e.g. 95% of glucose results < 75 mg/dL were within ± 15 mg/dL of the reference method, and for samples ≥ 75 mg/dL, 95% of results were within $\pm 20\%$ of the reference method. Results are summarized below:

Regression Analysis Healthcare Professional Palm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	1.049	- 5.972	0.954
Lot 2	1.025	- 1.897	0.966
Lot 3	0.995	- 3.030	0.951

Healthcare Professional Palm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	4/13(31%)	12/13(92%)	13/13(100%)
Lot 2	6/13(46%)	10/13(77%)	13/13(100%)
Lot 3	7/13(54%)	11/13(85%)	13/13(100%)

Healthcare Professional Palm vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	19/86(22%)	40/86(47%)	59/86(69%)	84/86(98%)
Lot 2	24/86(28%)	49/86(57%)	68/86(79%)	85/86(99%)
Lot 3	22/86(26%)	43/86(50%)	66/86(77%)	85/86(99%)

Regression Analysis Lay User Palm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.987	+ 3.191	0.980
Lot 2	0.960	+ 6.296	0.977
Lot 3	0.992	+ 4.803	0.976

Lay User Palm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	3/13(23%)	9/13(69%)	13/13(100%)
Lot 2	5/13(38%)	8/13(62%)	13/13(100%)
Lot 3	6/13(46%)	10/13(77%)	13/13(100%)

Lay User Palm vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	36/86(42%)	59/86(69%)	75/86(87%)	82/86(95%)
Lot 2	32/86(37%)	66/86(77%)	78/86(91%)	83/86(97%)
Lot 3	33/86(38%)	57/86(66%)	73/86(85%)	84/86(98%)

Regression Analysis Healthcare Professional Forearm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.999	+ 2.217	0.951
Lot 2	1.001	- 0.065	0.962
Lot 3	0.951	+ 8.097	0.949

Healthcare Professional Forearm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	4/13(31%)	11/13(85%)	13/13(100%)
Lot 2	9/13(69%)	13/13(100%)	13/13(100%)
Lot 3	3/13(23%)	11/13(85%)	13/13(100%)

Healthcare Professional Forearm vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	22/86(26%)	42/86(49%)	59/86(69%)	84/86(98%)
Lot 2	21/86(24%)	48/86(56%)	72/86(84%)	85/86(99%)
Lot 3	23/86(27%)	45/86(52%)	63/86(73%)	85/86(99%)

Regression Analysis Lay User Forearm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.981	+ 0.040	0.974
Lot 2	0.955	+ 3.611	0.981
Lot 3	0.981	+ 0.040	0.974

Lay User Forearm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	8/13(62%)	10/13(77%)	13/13(100%)
Lot 2	7/13(54%)	10/13(77%)	13/13(100%)
Lot 3	4/13(31%)	9/13(69%)	13/13(100%)

Lay User Forearm vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	38/86(44%)	62/86(72%)	73/86(85%)	84/86(98%)
Lot 2	31/86(36%)	62/86(72%)	74/86(86%)	85/86(99%)
Lot 3	31/86(36%)	52/86(60%)	71/86(83%)	83/86(97%)

Regression Analysis Healthcare Professional Upper arm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.992	+ 1.012	0.953
Lot 2	0.965	+ 3.959	0.951
Lot 3	1.050	- 7.418	0.966

Healthcare Professional Upper arm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	3/13(23%)	12/13(92%)	13/13(100%)
Lot 2	5/13(38%)	11/13(85%)	13/13(100%)
Lot 3	5/13(38%)	9/13(69%)	13/13(100%)

Healthcare Professional Upper arm vs YSI ≥ 75 mg/dL

Test Strip	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lot 1	22/86(26%)	41/86(48%)	65/86(76%)	85/86(99%)
Lot 2	22/86(26%)	41/86(48%)	61/86(71%)	83/86(97%)
Lot 3	23/86(27%)	40/86(47%)	66/86(77%)	86/86(100%)

Regression Analysis Lay User Upper arm vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.966	+ 0.945	0.960
Lot 2	0.930	+ 5.965	0.962
Lot 3	0.956	+ 3.116	0.968

Lay User Upper arm vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	6/13(46%)	10/13(77%)	13/13(100%)
Lot 2	6/13(46%)	9/13(69%)	13/13(100%)
Lot 3	6/13(46%)	8/13(62%)	13/13(100%)

Lay User Upper arm vs YSI ≥ 75 mg/dL

Test Strip	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lot 1	16/86(19%)	43/86(50%)	69/86(80%)	83/86(97%)
Lot 2	24/86(28%)	48/86(56%)	70/86(81%)	83/86(97%)
Lot 3	28/86(33%)	49/86(57%)	71/86(83%)	83/86(97%)

Regression Analysis Healthcare Professional Calf vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.910	+ 8.854	0.957
Lot 2	0.969	+ 4.297	0.939
Lot 3	0.964	+ 3.749	0.958

Healthcare Professional Calf vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	7/13(54%)	12/13(92%)	13/13(100%)
Lot 2	4/13(31%)	9/13(69%)	13/13(100%)
Lot 3	9/13(69%)	13/13(100%)	13/13(100%)

Healthcare Professional Calf vs YSI ≥ 75 mg/dL

Test Strip	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lot 1	28/86(33%)	50/86(58%)	66/86(77%)	85/86(99%)
Lot 2	16/86(19%)	38/86(44%)	53/86(62%)	84/86(98%)
Lot 3	24/86(28%)	45/86(52%)	66/86(77%)	84/86(98%)

Regression Analysis Lay User Calf vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.960	+ 5.430	0.965
Lot 2	0.983	+ 2.076	0.973
Lot 3	0.946	+ 9.490	0.969

Lay User Calf vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	6/13(46%)	11/13(85%)	13/13(100%)
Lot 2	7/13(54%)	13/13(100%)	13/13(100%)
Lot 3	6/13(46%)	11/13(85%)	13/13(100%)

Lay User Calf vs YSI ≥ 75 mg/dL

Test Strip	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lot 1	31/86(36%)	53/86(62%)	71/86(83%)	85/86(99%)
Lot 2	36/86(42%)	56/86(65%)	74/86(86%)	85/86(99%)
Lot 3	26/86(30%)	51/86(59%)	72/86(84%)	84/86(98%)

Regression Analysis Healthcare Professional Thigh vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	1.003	- 0.926	0.970
Lot 2	1.038	- 6.814	0.962
Lot 3	1.040	- 5.792	0.964

Healthcare Professional Thigh vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	5/13(38%)	12/13(92%)	13/13(100%)
Lot 2	8/13(62%)	10/13(77%)	13/13(100%)
Lot 3	7/13(54%)	10/13(77%)	13/13(100%)

Healthcare Professional Thigh vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	27/86(31%)	52/86(60%)	67/86(78%)	86/86(100%)
Lot 2	25/86(29%)	41/86(48%)	59/86(69%)	84/86(98%)
Lot 3	24/86(28%)	46/86(53%)	69/86(80%)	85/86(99%)

Regression Analysis Lay User Thigh vs YSI

Test Strip	Slope	Intercept	R ²
Lot 1	0.949	+ 3.698	0.970
Lot 2	0.930	+ 5.260	0.961
Lot 3	0.964	+ 3.338	0.955

Lay User Thigh vs YSI < 75 mg/dL

Test Strip	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lot 1	5/13(38%)	12/13(92%)	13/13(100%)
Lot 2	6/13(46%)	10/13(77%)	13/13(100%)
Lot 3	7/13(54%)	13/13(100%)	13/13(100%)

Lay User Thigh vs YSI ≥ 75 mg/dL

Test Strip	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Lot 1	34/86(40%)	54/86(63%)	70/86(81%)	84/86(98%)
Lot 2	30/86(35%)	50/86(58%)	65/86(76%)	83/86(97%)
Lot 3	25/86(29%)	47/86(55%)	66/86(77%)	83/86(97%)

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose values for normal people without diabetes is cited from the literature¹ and presented in the labeling as follows:

Fasting and before meal: 70 to 130 mg/dL

1-2 hours after meal: Less than 180 mg/dL

¹American Diabetes Association (2010), Standards of Medical Care in Diabetes. Diabetes Care 33 (Supplement 1): S11-S61.

N. Instrument Name:

Glucose Shepherd Blood Glucose meter

Glucose Shepherd Pro Blood Glucose meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 1.1 µL.

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 ☐ 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:

The glucose test is intended to be used with capillary whole blood from the finger, the palm, the forearm, the upper arm, the calf and the thigh. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

The Glucose Shepherd Blood Glucose meter is a no code device. Reaction intensities of new test strip lots must meet the manufacturer's no code criteria for use with these meters. Validation of new strip lots is confirmed by comparison to the YSI across the measuring range of the device.

6. Quality Control:

Glucose control solutions at three concentration levels can be run with this device. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. A usability study was performed to assess the readability of the labeling by recruiting 99 lay users (aged 22-72 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. These lay users also completed a questionnaire to indicate whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.
2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at grade levels ranging from 7.0th to 8.0th grade.
3. Customer service is available Monday to Friday between 8:30 AM to 4:30 PM CST. Toll free phone number is 1-877-394-1655 for customer support.
4. Insufficient sample studies were performed at volumes starting from 0.3 µL to 2.0 µL in increments of 0.1 µL around the recommended volume (1.1 µL) using six vials of test strips from one lot. Each sample was tested six times per strip lot. Three glucose concentration levels of venous whole blood were tested (49 mg/dL, 159 mg/dL and 248 mg/dL) as determined by the YSI. Appropriate sample volume was determined if the meter results compared to YSI results were within 10% bias for blood samples. A blood volume ≥ 1.1 µL met the criteria.
5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity below 85% R.H. The sponsor tested combinations of lowest and highest temperatures with lowest

and highest humidity levels. The study protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 50°F to 104°F (10°C to 40°C) and relative humidity below 85%.

6. The effect of altitude on the accuracy of the device was evaluated on the Glucose Shepherd Blood Glucose Monitoring System with two meters and four vials of test strips from one lot. Venous blood samples at five concentrations of glucose (50-100mg/dL, 101-150mg/dL, 151-200mg/dL, 250-300mg/dL and 400-450mg/dL) were tested at three altitude levels (3,328, 8,478 and 10,745 feet) and at sea level (22.97 feet). Each sample was also tested by YSI-2300. No significant interference from altitude was defined by the sponsor as bias within $\pm 10\%$. The data demonstrates that elevation of 10,745 feet does not affect the accuracy of the device. Based on the data, the sponsor claims that the Glucose Shepherd Blood Glucose Monitoring System can be used at altitude up to 10,745 feet.
7. The Glucose Shepherd Pro Blood Glucose Monitoring System is intended for multiple patient use by healthcare professionals and the Glucose Shepherd Blood Glucose Monitoring System is intended for home use by single person. Disinfection studies were performed on the Glucose Shepherd meter and lancing device to determine the robustness of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). CaviWipesXL (CW) disposable wipes (EPA Reg. No.46781-8) was validated, demonstrating complete inactivation of live virus for use with the Glucose Shepherd meter and lancing device. The sponsor demonstrated that there was no change in performance or in the external materials of the Glucose Shepherd meter after 15,000 cleaning and disinfection cycles to simulate an estimated 8 to 9 cleaning and disinfection cycles per day over 5 years of healthcare professional use. The sponsor demonstrated that there was no change in performance or in the external materials of the lancing after 3,000 cleaning and disinfection cycles. The labeling states that the meter must be replaced with a new meter at the end of 15,000 cleaning and disinfection cycles or 5 years, whichever comes first. The lancing device must be replaced with a new lancing device at the end of 5,000 cleaning and disinfection cycles or 1 year, whichever comes first. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures.
8. EMC testing was evaluated and certified by TUV Rheinland LGA Products GmbH and a certificate of conformity was issued to BroadMaster Biotech Corporation on 03-08-2010.
9. The effect of different hematocrit levels on the accuracy of the device was evaluated on the Glucose Shepherd Blood Glucose Monitoring System using two meters (tested in duplicate) and twelve vials of test strips from one lot. Blood

samples at nine hematocrit levels from 20% to 60% (20, 25, 30, 35, 40, 45, 50, 55 and 60%) were evaluated in eight concentrations of glucose of approximately 20, 50, 100, 200, 300, 400, 500 and 600 mg/dL. Glucose concentrations were compared to YSI and to 40% hematocrit. No significant interference from hematocrit was defined as bias within $\pm 15\%$. Results demonstrated that hematocrit levels between 20%-60% do not significantly interfere with glucose measurements.

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.