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

A. 510(k) Number:

k120989

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the finger and forearm, and venous whole blood

D. Type of Test

Quantitative amperometric assay (Glucose Dehydrogenase-FAD)

E. Applicant:

Nipro Diagnostic, Inc

F. Proprietary and Established Names:

TRUE METRIX™ Self Monitoring Blood Glucose System

TRUE METRIX PRO™-Professional Monitoring Blood Glucose System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW - Glucose test system	Class II	862.1345	Clinical Chemistry (75)
LFR – Glucose Dehydrogenase, Glucose	Class II	862.1345	Clinical Chemistry (75)
JJX – Single (Specified) Quality Control Material (Assayed and Unassayed)	Class I (reserved)	862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications below

2. Indication(s) for use:

   TRUE METRIX™ Self Monitoring Blood Glucose System

   The **TRUE METRIX™ Self Monitoring Blood Glucose System** is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX™ Self Monitoring Blood Glucose System is intended to be used by a single person and not be shared.

   The TRUE METRIX™ Self Monitoring Blood Glucose System 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. The TRUE METRIX™ Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

   The TRUE METRIX Test Strips are for use with the TRUE METRIX™ Self Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm.

   The TRUE METRIX Control Solution is for use with the TRUE METRIX Self Monitoring Meter and TRUE METRIX Test Strips to check that the meter and the test strip are working together properly and that the test is performing correctly.

   TRUE METRIX PRO™ Professional Monitoring Blood Glucose

   The **TRUE METRIX PRO Professional Monitoring Blood Glucose System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm and venous whole blood.

   The TRUE METRIX PRO Professional Monitoring Blood Glucose System is intended for multiple-patient use in professional healthcare settings. Testing is performed outside the body (*in vitro* diagnostic use) as an aid for monitoring the effectiveness of diabetes control. TRUE METRIX PRO Professional Monitoring Blood Glucose System is used only with single-use, auto-disabling lancing devices. The system is not to be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternative site testing can only be performed during steady-state blood glucose conditions.

   The TRUE METRIX PRO Test Strips are for use with the TRUE METRIX PRO Professional Monitoring Meter to quantitatively measure glucose (sugar) in fresh

capillary whole blood samples drawn from the fingertip or forearm and venous whole blood.

The TRUE METRIX Control Solution is for use with the TRUE METRIX PRO Professional Monitoring Meter and TRUE METRIX PRO Test Strips to check that the meter and test strip are working together properly and that the test is performing correctly.

Special conditions for use statement(s):

- For over-the-counter use and by healthcare professionals
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- TRUE METRIX Blood Glucose Meter and TRUE METRIX Blood Glucose Test Strips are for single-patient use only
- TRUE METRIX PRO Blood Glucose Meter is for multiple-patient use and should only be used with single-use, auto-disabling lancing devices.
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.

3. Special instrument requirements:

TRUE METRIX™ Blood Glucose Meter

TRUE METRIX PRO™ Blood Glucose Meter

I. Device Description:

The meter and test strips are marketed within a single package (Kit). Each of these components and glucose controls are available for purchase separately. Labeling included with the complete System consists of a detailed instruction booklet (Owner's Manual), test strip insert, glucose control insert, quick reference card, log book for recording test results, and a carrying case.

TRUE METRIX™ Self Monitoring Blood Glucose System consists of the following:

TRUE METRIX Blood Glucose Meter

TRUE METRIX Blood Glucose Test Strips (Calibration code embedded on strip) Glucose dehydrogenase-FAD (*Aspergillus sp.*), mediators, buffers and stabilizers.

TrueDraw Lancing Device

TRUE METRIX PRO™ Professional Monitoring Blood Glucose System consists of the following:

TRUE METRIX PRO Blood Glucose Meter

TRUE METRIX PRO Blood Glucose Test Strips (Calibration code embedded on strip) Glucose dehydrogenase-FAD (*Aspergillus sp.*), mediators, buffers and stabilizers.

For use with both the Self Monitoring and Professional Monitoring Blood Glucose Systems:

TRUE METRIX Control Solution (3 levels: 1 (26-56 mg/dL), 2 (98-132 mg/dL), 3 (256-346 mg/dL)) – aqueous D-Glucose solution with buffers, viscosity enhancing agent, salt, dye and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Ascensia Contour Blood Glucose System

   Glucose Meter-Check Control Solution for Bayer Ascensia Blood Glucose Test Systems

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

   k062058

   k082395

3. Comparison with predicate:

Similarities and Differences			
	Candidate Device		**Predicate (k062058)**
Type	TRUE METRIX Self Monitoring System	TRUE METRIX PRO professional Monitoring System	Contour System
Indications for Use/Intended Use	Same	Same	Test strips are for use with the meter to quantitatively measure glucose (sugar) in whole blood
Where Device Used	Home	Healthcare professional	Home, or by healthcare professional
Reagent Form	Same	Same	Electrochemical Test

			Strip
Assay/Detection Method	Same	Same	Electrochemical Biosensor
Sample Application	Same	Same	Whole blood/Control applied to portion of test strip that is external to the meter
Blood Sample Type	Capillary (fingertip, forearm)	Capillary (fingertip, forearm) and venous	Capillary (fingertip, forearm, palm and venous, arterial, neonate
Sample Size	0.5 µL	0.5 µL	0.6 µL
Measurement Range	20 – 600 mg/dL	20 – 600 mg/dL	10 – 600 mg/dL
Test Results	Plasma calibrated	Plasma calibrated	Plasma/serum calibrated
Power Source	Battery (One 3-volt lithium)	Battery (One 3-volt lithium)	Battery (Two 3-volt lithium)
Meter Memory Display	500 blood glucose test results; 1 glucose control test result	500 blood glucose test results; 1 glucose control test result	480 test results
Test Time	4 seconds	4 seconds	5 seconds
Units of Measure (mg/dL or mmol/L)	Same	Same	Factory set to mg/dL Cannot be changed by user
Date/Time appears with test result in display	Same	Same	Feature is available
Reagent Enzyme	Same	Same	Glucose Dehydrogenase-FAD
Meter calculates and displays glucose average values	Same	Same	Feature is available as 7, 14, and 30-day averages of blood results only
Identification of Control Solution and Results	Same	Same	Automatically distinguishes control solutions from whole blood samples
Daily Test Reminders	Up to 4 per day	Up to 4 per day	Up to 1 at a time
Hematocrit Range (%)	20 – 70	20 – 70	0 - 70
Results can be flagged	Alternative site results only	Alternative site results only	Pre-meal, Post-meal, log book
Altitude	Up to 10,150 ft.	Up to 10,150 ft.	Up to 10,000 ft.
Coding	Same	Same	Auto coding
Meter provides Ketone Test alert option	Feature is available	Feature is available	Feature is not available

Meter displays day of week with glucose result	Feature is available	Feature is available	Feature is not available

Similarities and Differences		
	Candidate Device	**Predicate (k062058)**
Type	TRUE METRIX Control Solution	Glucose Meter-Check Control Solution
Indications for Use/Intended Use	Same	The control solution is for use with the meter and test strips to check that the meter and test strip are working together properly and that the test is performing correctly
Analyte	Same	D-Glucose
Matrix	Same	Aqueous
Color	Same	Red
Levels	3	1

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

EN ISO 15197:2003 *In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus*

EN 13640:2002 *Stability Testing of in vitro Diagnostic Reagents*

ISO 14197:2007 *Medical devices - Application of risk management to medical devices*

NCCLS (CLSI) GP14-A:1996 *Labeling of Home-Use In Vitro Testing Products*

L. Test Principle:

The TRUE METRIX/TRUE METRIX PRO Blood Glucose Test Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUE METRIX Meter, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or TRUE METRIX Glucose Control Solution are drawn into the sample well of the strip, glucose in the sample reacts with the chemicals and produces an electrical current. The meter measures the current and calculates the amount of glucose. The result is displayed as a plasma equivalent value.

M. Performance Characteristics (if/when applicable):

The TRUE METRIX Self Monitoring and TRUE METRIX Pro Professional Monitoring Blood Glucose Systems use the same test strip. The systems differ only in the names, intended use (single-patient versus multi-patient), and claimed sample sites (venous blood can be used with multiple patient version). Therefore only one set of data is presented below.

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability – Within Run

The sponsor performed within-run precision studies using venous whole blood samples adjusted to five different glucose concentrations within the following ranges: 36 to 44, 76 to 84, 133 to 147, 190 to 210, and 304 to 336 mg/dL. Each glucose level was analyzed in replicates of 10 on 10 meters. Results for within-run are summarized below:

Lot 1	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
[Conc.]	36-44 mg/dL	76-84 mg/dL	133-147 mg/dL	190-210 mg/dL	304-336 mg/dL
Mean (mg/dL)	40	87	137	211	318
SD (mg/dL)	1.6	2.4	4.2	4.8	10.1
%CV	4.1	2.7	3.1	2.3	3.2
n	100	100	100	100	100

Lot 2	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
[Conc.]	36-44 mg/dL	76-84 mg/dL	133-147 mg/dL	190-210 mg/dL	304-336 mg/dL
Mean (mg/dL)	42	74	142	218	336
SD (mg/dL)	1.5	3.4	6.4	9.1	13.5
%CV	3.6	4.6	4.5	4.2	4.0
n	100	100	100	100	100

Pooled	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
[Conc.]	36-44 mg/dL	76-84 mg/dL	133-147 mg/dL	190-210 mg/dL	304-336 mg/dL
Grand Mean (mg/dL)	41	81	139	214	327
Pooled SD (mg/dL)	1.8	3.5	5.6	7.9	12.4
Pooled %CV	4.3	4.3	4.0	3.7	3.8
n	200	200	200	200	200

Intermediate precision – Between day

Intermediate precision was evaluated using three levels of glucose control solutions with approximate concentrations of: 40, 120, and 350 mg/dL. Each glucose level was analyzed once per day on 10 meters over 10 days. Results for intermediate, between-day per lot precision are summarized below:

Lot 1	Control L1	Control L2	Control L3
Mean (mg/dL)	30	99	275
SD (mg/dL)	1.1	3.0	11.8
%CV	3.5	3.0	4.3
n	100	100	100

Lot 2	Control L1	Control L2	Control L3
Mean (mg/dL)	30	109	304
SD (mg/dL)	1.2	3.7	10.5
%CV	3.9	3.4	3.5
n	100	100	100

Pooled	Control L1	Control L2	Control L3
Grand Mean (mg/dL)	30	104	290
Pooled SD (mg/dL)	1.1	3.4	11.2
Pooled %CV	3.7	3.2	3.9
n	200	200	200

b. Linearity/assay reportable range:

Linearity was evaluated using 9 venous blood samples with glucose concentrations of 21, 43, 78, 163, 239, 329, 400, 507, 586 mg/dL (as measured by YSI) using 2 test strip lots, 8 meters for a total of 16 replicates per glucose level (144 total). The values from the meter were compared with those obtained from YSI Blood Glucose Analyzer. Results from the regression analyses are included below:

Lot	1	2	Pooled
n	72	72	144
Slope	0.985	0.989	0.987
y-int. (mg/dL)	2.14	2.30	2.22
r^2	0.999	0.999	0.999

The results of the study support the sponsor's claimed glucose measurement range of 20 - 600 mg/dL.

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

Traceability

The TRUE METRIX Self Monitoring Blood Glucose System and the TRUE METRIX Pro™ Professional Blood Glucose System are traceable to the NIST SRM 917c glucose. The method comparison study was performed using the candidate device and YSI 2300 and 2900 glucose analyzers as the reference method.

Test Strip Stability:

Test strip stability was assessed in accelerated and real time studies. Testing protocols and acceptance criteria for the TRUE METRIX blood glucose test strips were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 24 months and an open-vial stability of 4 months at the recommended storage temperatures of 40°F to 86°F and 10-85% relative humidity (RH).

Control Solution Value Assignment and Stability:

Value assignment: Three levels of aqueous control solutions (levels 1, 2, 3) are available for use with the TRUE METRIX™ Self Monitoring Blood Glucose System and the TRUE METRIX PRO™ Professional Blood Glucose System. The value ranges for each of the control solutions are assigned by repeat analysis using three lots of TRUE METRIX strips. The mean, SD and CV are used to establish the ranges for each control solution which are provided on the test strip vial label.

Stability Testing: Stability was assessed using real-time and accelerated testing for

each control solution level. Protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claim of 24 months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 36°F to 86°F.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity study in Section M1b above.

d. Analytical specificity:

To assess potential interference the sponsor used venous whole blood samples adjusted to 2 different glucose levels of approximately 75 and 240 mg/dL. Each of these samples was divided into three spiked with aliquots the following levels of interferent: a normal/therapeutic level, an abnormal/toxic level and a control pool (no interferent). Each sample was analyzed once per meter per test strip lot for a total of 16 measurements per sample. The % bias between the interferent containing sample and the control sample was calculated. The sponsor defines no significant interference as ≤10% difference relative to the control sample. No interferences were observed with the concentrations of interferents tested below: (exception: xylose)

Potential Interfering Substance	**Concentration**		**Potential Interfering Substance**	**Concentration**	
	Low (mg/dL)	**High (mg/dL)**		**Low (mg/dL)**	**High (mg/dL)**
Acetaminophen	2	30			
Acetone	2	20	Ibuprofen	4	50
Acetylcystiene	3.4 mM	10.2 mM	L-Dopa	1.33	4
Ascorbic Acid	1.2	6	Maltose	125	250
Bilirubin	1	15	Maltotetraose	35	70
Caffeine	1.25	6	Maltotriose	90	180
Cholesterol	150	250	Metformin	0.4	4
Creatinine	1.5	5	Methyldopa	0.4	1.5
Dopamine	0.03	0.1	Naproxen Sodium	8	50
Ethanol	150	400	Salicylic acid	2	20
Sodium Fluoride	0.05	857	Tetracycline	0.35	1.5
Galactose	5	15	Tolazamide	2.5	5
Gentisic Acid	0.4	1.8	Tolbutamide	8.1	64
Glipizide	0.15	0.2	Triglycerides	150 500	1000
Hemoglobin	150	~1400	Uric Acid	3	9
			Xylose	5	58

Xylose did not meet interference acceptance criteria and additional testing was conducted to determine the interference point. Xylose interferes at ≥ 7 mg/dL.

The sponsor has the following limitations in their labeling:

Xylose: Do not use System during a xylose absorption test. Blood samples containing xylose concentrations >7 mg/dL may falsely raise your System glucose results. Please check with your Doctor before using the System.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:

To assess system accuracy, results from the TRUE METRIX Blood Glucose System were compared to a reference method, YSI. Finger (100 participants) and forearm (separate study, 112 participants) capillary samples with glucose concentrations ranging from 32 – 508 mg/dL and 52 - 392 mg/dL (according to reference), respectively, were tested using three test strip lots. To obtain blood glucose concentrations <50 mg/dL and > 400 mg/dL, 4 samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. The results relative to YSI are summarized in the tables below:

Fingerstick

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
9/12 (75%)	11/12 (92%)	12/12 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
54/88 (61%)	78/88 (89%)	88/88 (100%)	88/88 (100%)

Fingerstick regression analysis

n	100
Slope (95% CI)	1.03 (1.01-1.04)
y-int. (mg/dL) (95% CI)	1.12 (-2.54-4.79)
r^2	0.99
Range (mg/dL)	32-508

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
5/9 (56%)	9/9 (100%)	9/9 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
42/103 (41%)	74/103 (72%)	97/103 (94%)	102/103 (99%)

Forearm regression analysis

n	112
Slope (95% CI)	1.01 (0.99 – 1.04)
y-int. (mg/dL) (95% CI)	4.16 (-0.08 – 8.39)
r^2	0.98
Range (mg/dL)	52 - 392

b. Matrix comparison:

Venous

To assess the performance of the True Metrix Blood Glucose System using venous blood, 101 venous (sodium heparin) samples were used containing glucose concentrations of 58 to 405 mg/dL (as measured by the reference method). The results obtained from the True Metrix system were compared to results obtained using the reference method (YSI) and are summarized below:

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
3/4 (75%)	4/4 (100%)	4/4 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
33/97 (34%)	73/97 (75%)	89/97 (92%)	96/97 (99%)

Venous regression analysis

n	101
slope	1.07
y-intercept (mg/dL	-1.15
r^2	0.98
Range (mg/dL)	58 – 405

Anticoagulants

Venous blood was drawn from 40 subjects having glucose ranges from 72 – 322 mg/dL. The donor blood was collected into each of 3 vacutainer tubes (lithium heparin, sodium heparin, and EDTA). Results of the study demonstrate no significant bias when results from samples containing EDTA, lithium heparin, or sodium heparin were compared to results from the same samples measured by YSI. ISO tables and regression analyses are in the tables below:

Sodium Heparin

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
1/1 (100%)	1/1 (100%)	1/1 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
10/39 (26%)	25/39 (64%)	35/39 (90%)	39/39 (100%)

Sodium heparin regression analysis

n	40
slope	1.06
y-intercept (mg/dL	2.45
r^2	0.98
Range (mg/dL)	72 – 322

Lithium heparin

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
1/1 (100%)	1/1 (100%)	1/1 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
5/38 (13%)	18/38 (47%)	35/38 (92%)	37/38 (97%)

Lithium heparin regression analysis

n	39
slope	1.08
y-intercept (mg/dL	0.75
r^2	0.98
Range (mg/dL)	73 – 316

EDTA

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
1/1 (100%)	1/1 (100%)	1/1 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
9/37 (24%)	25/37 (68%)	31/37 (84%)	37/37 (100%)

EDTA regression analysis

n	38
slope	1.02
y-intercept (mg/dL	5.48
r^2	0.96
Range (mg/dL)	73 – 319

The sponsor has the following in their labeling:

Venous whole blood collected in sodium/lithium heparin (green top) or EDTA (purple top) tube may be used for testing. Mix well before use.

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):

Lay-User Performance Study:

To assess the performance of the TRUE METRIX Self-Monitoring Blood Glucose System in the hands of the lay-users the sponsor performed two separate studies; one for finger, one for forearm. Lay-user participants collected 233 fingerstick samples, and 112 forearm samples (separate study). Results were analyzed by comparing blood glucose results from the TRUE METRIX meter obtained by the lay user against the YSI reference value. The samples ranged from 60 – 462 (fingerstick) and 52 to 392 mg/dL (forearm) as measured by YSI. The results are summarized in the tables below:

Fingerstick

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
10/17 (59%)	16/17 (94%)	17/17 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
129/216 (60%)	192/216 (89%)	212/216 (98%)	214/216 (99%)

Fingerstick regression analysis

n	233
Slope (95% CI)	1.02 (1.01-1.04)
y-int. (mg/dL) (95% CI)	-0.17 (-3.17-2.82)
r^2	0.98
Range (mg/dL)	60-462

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
7/11 (64%)	10/11 (91%)	11/11 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
46/101 (46%)	75/101 (74%)	95/101 (94%)	97/101 (96%)

Forearm regression analysis

n	112
Slope (95% CI)	1.01 (0.98 – 1.04)
y-int. (mg/dL) (95% CI)	3.82 (-0.73 – 8.38)
r^2	0.98
Range (mg/dL)	52 – 392

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

Expected glucose values without diabetes:

Status	Range
Fasting	<100 mg/dL
Two hours after meals	<140 mg/dL

American Diabetes Association: Standard of Medical Care in Diabetes 2011, Diabetes Care, vol.34, supplement 1, S11-S61, January 2011.

N. Instrument Name:

TRUE METRIX™ Blood Glucose Meter

TRUE METRIX PRO™ Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.5 μL.

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

   Yes _____ or No __X___.

   The sponsor has included ports for data transfer to a computer, but they are not functional.

   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 venous whole blood and capillary whole blood from the finger or forearm only. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   No-Coding System: The user is not required to enter a test strip lot specific Calibration Code into the meter by pressing a button or inserting a Code Chip. Test strip lot-specific calibration is accomplished by embedding the Calibration Code onto each test strip, which then provides the Calibration Code information to the meter when the test strip is inserted into the meter. The test strip provides the meter with the optimal Calibration Code parameters determined for the specific test strip lot.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available with this system (Manufactured by Bionostics, Inc.). Control solutions are sold separately. When a control solution is applied, the meter automatically detects and identifies the glucose control sample prior to displaying the glucose measurement. The meter identifies that the measurement is from a control sample by displaying the "Control Symbol" in the meter display. 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. Hematocrit Study: The effect of different hematocrit levels on the performance of the TRUE METRIX Blood Glucose System was evaluated using venous whole blood samples with hematocrit levels of 20, 25, 42, 55, 60, 65% and 70%, at glucose concentrations of 40, 95, 150, 300, 500 mg/dL. Each sample was then tested 8 times using the TRUE METRIX meter and the values were compared with those obtained from YSI analyzer.
2. Altitude study: Venous whole blood samples collected and adjusted to obtain 5 glucose concentrations: 50, 100, 180, 250, 500 mg/dL (43% hematocrit) were tested at 13 and 10,150 feet above sea level. Results were compared to YSI values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,150 feet have no significant effect on blood glucose measurements from the TRUE METRIX glucose meter.
3. Temperature and Humidity studies: The sponsor performed temperature and humidity studies using venous blood samples at 70, 250 and 500 mg/dL to evaluate temperatures ranging from 5 to 40^{o}C (41 to 104 ^{o}F) and relative humidity from 10% to 90%. Meter results were compared to YSI values. Eight temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, average temperature/low humidity, average

temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. No significant bias (relative to YSI) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 43 to 100°F (6.1 – 37.8 °C) with relative humidity of 10 to 90%.

4. Sample Volume Study: The sponsor performed a study to verify the test strip minimum sample volume requirement (0.5 µL) and the test strip fill error requirement established for the TRUE METRIX Blood Glucose System. Blood samples (100 mg/dL) were tested at six sample volumes (0.29, 0.38, 0.43, 0.47, 0.51, 0.56 µL) and values obtained were compared to YSI values. The system displays an error code for insufficient sample volume. Results support the claimed sample volume of 0.5 µL.
5. Readability Evaluation: Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were written at the 7th grade level.
6. Electromagnetic compatibility (EMC) testing was performed by Intertek Testing Services NA Inc., Duluth Georgia, an accredited CB testing laboratory. Verification of Compliance certificates were provided. Testing was found to be adequate for the True Metrix System.
7. Infection Control Studies: The device is intended for single-patient and professional use. PDI Super Sani-Cloth wipes (EPA registration #9480-4) were validated through disinfection efficacy studies demonstrating complete inactivation of live virus using materials comprising the meter and lancing device. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter and lancing device (for use only with the single-pateint use systems) after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter and >3 years of lancing device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
8. True Metrix Customer Care Service Center is available 24 hours a day, 365 days a year by calling 1-800-803-6025.

Q. Proposed Labeling:

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

R. Conclusion:

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