

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

A. 510(k) Number:

k113077

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric assay
(Glucose Oxidase)

E. Applicant:

Taidoc Technology Corporation

F. Proprietary and Established Names:

Bioland G-423 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, Blood Glucose Test System, Over-the-Counter
CGA, Glucose Oxidase, Glucose
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below

2. Indication(s) for use:

The Bioland G-423 BLOOD GLUCOSE MONITORING SYSTEM is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This system is intended to be used by a single person and should not be shared.

The Bioland G-423 Blood Glucose Monitoring 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 Bioland G-423 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The Bioland G-423 Test Strips are for use with the Bioland G-423 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):

- Not for use with neonates
- For In Vitro diagnostic use only
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients
- Allows testing on the fingertip only
- For single patient use only

4. Special instrument requirements:

Bioland G-423 Blood Glucose Meter

I. Device Description:

The Bioland G-423 Blood Glucose Monitoring System, Model G-423 is comprised of the G-423 Blood Glucose Meter, G-423 Blood Glucose Test Strips, Taidoc control solution cleared under k093724 and Lancet device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Prodigy Blood Glucose System

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

k053593

3. Comparison with predicate:

Similarities and Differences		
Device	Predicate (k053593)	Candidate Device (G-423)
Indications for use	Intended to be used for the quantitative measurement of glucose in capillary whole blood from the fingertip. It is intended for use by people with diabetes mellitus at home (Over-the Counter) as an aid in monitoring the effectiveness of diabetes control program.	Same as predicate
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same as predicate
Enzyme	Glucose oxidase	Same as predicate
Power source	1 x CR2032 battery (3V)	Same as predicate
Temperature compensation	Automatic compensation with built-in thermister	Same as predicate
Reaction time (sec)	10	Same as predicate
Measurement range	20-600 mg/dL	Same as predicate
Operating condition	50 °F - 104°F (4°C - 40°C), below 85% R.H.	50 °F - 104°F (4°C - 40°C), below 90% R.H.
Test Strip Calibration	Use code strip to calibrate the meter	Same as predicate
Measurement mode	General and control solution	Same as predicate
Special message	Lo/Hi/Ketone	Same as predicate
Power saving	Auto turn-off after 3 minutes without action	Same as predicate
Test Strip	Revolution Blood Glucose Test Strip	Bioland G-423 Blood Glucose Test Strips
Sample volume	1.8µL	Same as predicate
Test Strip chemical component	10% Glucose oxidase (A. niger) 50% Electron shuttle 8% Enzyme protector 32% Non-reactive ingredients	Same as predicate
Strip Storage/ Transportation condition	39.2F-104F(4°C - 40°C), below 85% R.H.	Same as predicate
Memory feature	450 measurements	180 measurements
Size Length x width x height	88mm(L) x 62mm(W) x 22mm(H)	81mm(L) x 62mm (W) x 19mm (H)

Weight (excl. battery)	46.5g	54.6g
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K. Standard/Guidance Document Referenced (if applicable):

- IEC/EN 60601-1-2: (2011): Medical electrical equipment Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests-Edition 2.1; Edition 2:2001 consolidated with amendment 1:2004
- ISO 15197:2003, *In Vitro* Diagnostic Test Systems—Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus
- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- CLSI/NCCLS EP7-A; Interference Testing in Clinical Chemistry; Approved Guideline
- CLSI EP6-P2 Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Proposed Guideline
- IEC/EN 61010-1 / 2001; Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements
- EN 13640:2002 Stability testing of in vitro diagnostic medical devices
- CLSI EP9-A: Method comparison and bias estimation using patient samples; approved guideline

L. Test Principle:

The Bioland G-423 Blood Glucose Monitoring System, Model G-423 uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated repeatability evaluation and intermediate precision studies using a protocol based on the ISO 15197. Five levels of venous whole blood over the claimed assay range were used to establish repeatability of the assay. Each sample was analyzed on ten Bioland G-423 glucose meters by one operator using three lots of test strips, for a total of 300 measurements per meter per level. Results are summarized in the following tables:

Individual Lot Results (Mean of 10 meters):

Level 1:	Lot 1	Lot 2	Lot 3
Mean glucose (mg/dL)	39.7	39.9	40.1
Std Dev	1.4	1.5	1.4
% CV	3.5	3.7	3.5

Level 2:	Lot 1	Lot 2	Lot 3
Mean glucose (mg/dL)	88.6	88.2	88.8
Std Dev	2.3	2.2	2.5
% CV	2.6	2.5	1.7

Level 3:	Lot 1	Lot 2	Lot 3
Mean glucose (mg/dL)	141.7	141.7	142.2
Std Dev	2.5	2.4	2.5
% CV	1.7	1.7	1.7

Level 4:	Lot 1	Lot 2	Lot 3
Mean glucose (mg/dL)	200.1	200.1	199.7
Std Dev	5.3	5.5	8.6
% CV	2.6	2.7	2.9

Level 5:	Lot 1	Lot 2	Lot 3
Mean glucose (mg/dL)	301.4	300.9	301.5
Std Dev	8.6	8.6	9.1
% CV	2.9	2.9	3.0

Summary of Results:

Level # (glucose range mg/dL)	Mean	SD	%CV
Level 1 (30 – 50)	39.9	1.43	---
Level 2 (51 – 100)	88.5	2.26	2.55
Level 3 (111 – 150)	141.9	2.46	1.73
Level 4 (151 – 250)	199.9	5.24	2.71
Level 5 (251 – 400)	301.3	8.77	2.91

In addition, the intermediate precision was tested using three levels of control solutions. (Level 1, 30 – 50; Level 2, 96 – 144 and Level 3, 280-420 mg/dL). Each sample was tested on ten glucose meters, with three strip lots for a total of ten days. %CV was calculated for levels 2 and 3 only. Results are summarized in the following table:

Individual Lot Results (Mean of 10 Meters):

Level 1 (30-50 mg/dL)	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	39.7	39.6	40.0
SD (mg/dL)	2.3	2.3	2.1

Level 2 (96-144 mg/dL)	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	120.0	120.2	119.7
SD (mg/dL)	3.6	3.4	4.1
CV (%)	3.0	2.8	3.4

Level 3 (280-420 mg/dL)	Lot 1	Lot 2	Lot 3
Mean (mg/dL)	301.3	301.1	301.0
SD (mg/dL)	8.0	7.9	7.4
CV (%)	2.6	2.6	2.5

Summary of Results:

Level# (glucose range mg/dL)	Mean	SD	%CV
Level 1 (30 – 50)	39.8	2.25	---
Level 2 (96 – 144)	120	2.54	2.94
Level 3 (280 – 420)	301	7.42	2.46

b. Linearity/assay reportable range:

To determine the linearity regression of the candidate device, venous whole blood samples with nine different blood glucose levels, spanning the entire measuring range (15 to 621 mg/dL), and hematocrit adjusted to 40+/-2% were tested with three strip lots and two Bioland G-423 glucose meters. The YSI 2300D glucose analyzer was used as the reference method.

Linear Regression Analysis:

Lot 1: $y = 0.9929 x + 1.4924, r^2 = 0.9999$

Lot 2: $y = 0.9996 x + 0.8969, r^2 = 0.9998$

Lot 3: $y = 0.9972 x + 0.0323, r^2 = 0.9991$

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

The method comparison was performed using the proposed devices and YSI 2300 glucose analyzer.

Stability: The storage claims for this device are: 90 days for open vial of strips stored at 35.6 – 89.6 °F (2 – 32 °C) and 12 months for unopened vials of strips stored at 2 - 32°C. The study protocols (accelerated testing and real time studies), summary of results and acceptance criteria were reviewed and found to be adequate.

Control Solutions were previously cleared under k093724.

d. Detection limit:

The measuring range of the system is 20 to 600 mg/dL. This range was verified by the linearity study above.

e. Analytical specificity:

The sponsor performed interference studies with spiked venous blood samples at three glucose concentrations (Level 1 (~75-80 mg/dL), Level 2 (~120 mg/dL) and Level 3 (~300 mg/dL)) that were prepared and divided into a test (dosed) pool and a control pool. The interferents were added to the sample and each sample was analyzed using two test strip lots and three glucose meters. The YSI 2300D glucose analyzer was used as the reference method. The bias between control and dosed samples were calculated for each substance. The table below lists all substances tested at concentrations with insignificant (<10%) interference:

Substance	Concentration with <10% interference (mg/dL)
Acetaminophen	<5
Allopurinol	5
Ascorbic acid	4
Aspirin	60
Bilirubin	20
Cholesterol	500
Creatinine	5
Dopamine	<1.25
Galactose	1000
Ibuprofen	55
Lactose	1000
L-Dopa	<0.7
Maltose	1000
Methyl Dopa	<0.625
Tetracycline	4
Tolbutamide	50
Xylose	<6.25
Uric Acid	<10

The following warning statement is included in the test strip insert:

- Acetaminophen at concentration of 5 mg/dL and higher interferes with glucose concentration reading
- Dopamine at concentration of 1.25 mg/dL and higher increases glucose concentration reading
- L-dopa at concentration of 0.7 and higher increases glucose concentration reading
- Methyldopa at concentration of 0.625 mg/dL and increases glucose concentration reading
- Xylose at concentration of 6.26 mg/dL and higher increases glucose concentration reading
- Uric acid at concentration of 10 mg/dL and higher increases glucose concentration reading

f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method Comparison:

The sponsor conducted a combined accuracy and consumer study with trained operators and a total of 182 lay-users. Each lay user participant performed their own fingerstick and tested their blood on the Bioland G-423 meter using only the instructions in the user’s manual and test strip insert. A trained operator then performed a second fingerstick and tested the blood on the same meter. Venous whole blood was also collected and measured on an YSI analyzer. The total range of samples tested was 35 to 578 mg/dL, with a hematocrit range of 31.3-54.4%. A total of 20 samples (11 samples < 50 mg/dL and 9 samples > 400 mg/dL) were glycolyzed or spiked, respectively and tested by trained operators only. Linear regression results are presented below:

Trained operator vs. YSI-2300	$y = 1.024 x - 1.602, r^2 = 0.9901, x = 202$
Lay user vs. YSI-2300	$y = 1.013 x + 1.273, r^2 = 0.9870, x = 182$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ± 15 mg/dL of the YSI results at glucose concentrations <75mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Trained operators	9/31 (29%)	27/31 (87.1%)	31/31 (100%)
Lay users	6/20 (30%)	18/20 (90%)	20/20 (100%)

For glucose concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Trained operators	85/171 (49.7%)	156/171 (91.2%)	171/171 (100%)	171/171 (100%)
Lay users	73/162 (45%)	150/162 (92.6%)	161/162 (99.4%)	161/162 (99.4%)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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:

The device labeling contains the following reference range statement from the American Diabetes Association Clinical Practice Recommendations (2012, Diabetes Care, V35 S1: S1-100).

Time of Day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 104 mg/dL (7.8 mmol/L)

N. Instrument Name:

Bioland G-423 Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings. Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

Yes ___ or No x

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

Yes ___ or No x

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes x or No ___

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood samples from the finger. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number is associated with the meter by inserting a test strip and requires entering the code number to match that found on the test strip bottle. No further calibrations are required of the user.

6. Quality Control:

Controls are not included in the G-423 Blood Glucose Monitoring System, but the labeling explains which controls should be used with the meter. The labeling also provides recommendations on when to test control materials. The meter will read the control solution just like a blood sample, and control results are displayed but not stored in memory. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is told to contact customer support.

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

1. Infection Control Studies:

The device system is intended for single-patient use. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach by CALTECH wipes (EPA Registration # 59894-10-37549). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 5000 cleanings and 5000 disinfection steps with the DISPATCH® Hospital Cleaner Disinfectant Towels with Bleach by CALTECH wipes (EPA Registration # 59894-10-37549). The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2. Hematocrit study:

To study the effect of hematocrit, venous blood samples at six glucose concentrations (~30 mg/dL, 75 mg/dL, 150 mg/dL, 250 mg/dL, 400 mg/dL and 500 mg/dL) and hematocrit adjusted to 20, 25, 30, 35, 40, 45, 50, 55, 60, 65 and 70 were evaluated on the Bioland G-423 Blood Glucose Monitoring System and compared to the YSI values. In addition, measurements obtained on the Bioland glucose meter were compared to a normal hematocrit (40%). The data supports the sponsor’s claim that hematocrit 15%-55% does not significantly interfere (more than $\pm 15\%$) with glucose measurements using the test system.

3. Altitude study:

An altitude study was performed at elevations up to 10,774 feet with 5 different concentrations of glucose spiked venous whole blood spanning 30 to 500 mg/dL glucose range. Sea level results (98 feet above sea level) were compared to results at higher elevations and to YSI values and were found to be acceptable.

4. Temperature and humidity studies:

Temperature and humidity studies were conducted to demonstrate that the Bioland G-423 device can be used at temperatures of 50 to 104°F (4 to 40°C) and at a relative humidity from 60% to 90%, and stored at temperatures of -4 to 140°F (-20 to 60°C) with a relative humidity from 60% to 90%. Studies were conducted with combinations of temperature and humidity to include low temperature and low humidity, low temperature and high humidity, high temperature and low humidity, and high temperature and high humidity. Study results were reviewed and were found to be acceptable, supporting the sponsor stated temperature and humidity claims.

5. Electromagnetic Interference Studies:

Additional electromagnetic interference study was performed to verify these new

products. The results of this study complied with standards listed in the Standard/Guidance Document Referenced section above.

6. Specimen volume study:

A study to evaluate the effect of different sample volumes (1.00, 1.10, 1.20, 1.35, 1.50, 1.65, 1.80 and 2.50µl) was conducted to demonstrate that the meter requires a minimum of 1.8 µl volume to obtain an accurate reading.

7. Readability:

The sponsor provided a readability study and obtained Flesch-Kincaid grade level scores of 8 or lower for the User's Manual (6.5), test strips (7.8).

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.