Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

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

I Background Information:

A 510(k) Number

K191657

B Applicant

Bioland Technology Ltd.

C Proprietary and Established Names

Bioland Blood Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in fresh capillary whole blood samples obtained from the fingertip

C Type of Test:

Quantitative amperometric assay (glucose oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Bioland Blood Glucose Monitoring System is comprised of Bioland Blood Glucose Meter and Bioland Blood Glucose Test Strips.

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

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician's offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as 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.
- The blood monitoring system is not intended for use on neonates.
- Altitudes above 10744 feet (3275 meters) may cause inaccurate results.
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
- Very low (less than 20%) or very high (more than 60%) red blood cell count (hematocrit) can lead to incorrect test results. If you do not know your hematocrit level, please consult your health care provider.
- High temperature (more than 104°F) and low temperature (less than 50°F) may lead to incorrect test results.
- High humidity (more than 85%) and low humidity (less than 10%) may lead to incorrect test results.

D Special Instrument Requirements:

Bioland Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The Bioland Blood Glucose Monitoring System consists of the Bioland Blood Glucose Meter, Bioland Blood Glucose Test Strips, lancing device, sterile lancets and Bioland Glucose Control Solutions (Levels 1, 2 and 3).
Bioland Blood Glucose Test Strips and Bioland Glucose Control Solutions (Levels 1, 2 and 3) are not included in the kit package and should be purchased separately.

B Principle of Operation:

The Bioland Blood Glucose Monitoring System quantitatively measures the amount of glucose in whole blood from the fingertip using amperometric technology. The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase and a mediator on the test strip. The detected current signal is proportional to the glucose concentration in the sample, which is then calculated and displayed on the meter.

C Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Bioland Blood Glucose Meter.

2. Specimen Identification:

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

3. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   The meter does not require calibration or coding by the user.

5. Quality Control:
   Bioland Glucose Control Solutions are aqueous solutions containing glucose and are available at three levels (Level 1, 2 and 3). Instructions on how to order control solutions, and when to perform a control solution test are included in the user guide. The control solution readings are not included in the average of the patient results when the measurements are performed in the 'CTL' measurement mode. The user is cautioned not to use the meter and to contact the customer support if the control result falls outside these ranges the range printed on the test strip vial label.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Bioland G-423 Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K113077

C Comparison with Predicate(s):

Device & Predicate Device(s):	K191657	K113077
Device Trade Name	Bioland Blood Glucose Monitoring System	Bioland G-423 Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	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
Test Principle	Amperometric glucose biosensor	Same
Enzyme	Glucose Oxidase	Same
Specimen Type	Capillary whole blood from fingertip	Same

Device & Predicate Device(s):	K191657	K113077
Detecting Range	40 ~ 600 mg/dL	Same
General Device Characteristic Differences		
Test Strip Calibration	No Code function, no need to calibrate the meter	Use Code test strip to calibrate the meter
Sample volume	≥ 0.7 μL	≥ 1.8 μL
Measuring Time	6 s	10 s

VI Standards/Guidance Documents Referenced:

FDA Guidance Document; Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, issued on October 11, 2016

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

CLSI, EP06-A: 2003, Evaluation of the linearity of quantitative analytical Methods: A Statistical Approach.

CLSI EP07-A2: 2005, Interference Testing in Clinical Chemistry, Approved Guideline, 2nd Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run precision studies were performed using venous whole blood samples adjusted to five glucose concentration levels: 40.3, 89.9, 131.5, 199.3 and 323.8 mg/dL. Each glucose level was analyzed in replicates of 10, using 3 lots of test strips and 10 meters for a total of 300 measurements per each glucose level. Results are summarized below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (30-50)	1	100	40.0	2.7	6.6
	2	100	40.2	2.7	6.7
	3	100	40.0	2.5	6.3

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
	Combined	300	40.1	2.6	6.5
Level II (51-110)	1	100	89.7	3.1	3.5
	2	100	90.2	3.1	3.5
	3	100	89.9	3.1	3.4
	Combined	300	89.9	3.1	3.5
Level III (111-150)	1	100	130.8	4.6	3.5
	2	100	130.0	4.7	3.6
	3	100	130.7	4.6	3.5
	Combined	300	130.5	4.6	3.6
Level IV (151-250)	1	100	200.0	7.2	3.6
	2	100	199.9	6.5	3.3
	3	100	201.3	7.0	3.5
	Combined	300	200.4	6.9	3.4
Level V (251-400)	1	100	322.1	11.1	3.4
	2	100	323.2	10.9	3.4
	3	100	320.9	10.1	3.1
	Combined	300	322.1	10.7	3.3

Intermediate (day-to-day) precision was evaluated using 5 levels of glucose control solutions with concentrations of 41.9, 94.0, 131.1, 199.2 and 325.3 mg/dL. For each concentration, 10 measurements were taken over 10 days using 10 meters and 3 lots of test strips, for a total of 300 measurements per sample. Results are summarized below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (30-50)	1	100	40.1	2.0	5.1
	2	100	40.1	2.0	5.1
	3	100	40.0	1.9	4.9
	Combined	300	40.1	2.0	5.0
Level II (51-110)	1	100	90.5	2.5	2.8
	2	100	90.3	2.7	3.0
	3	100	89.8	2.5	2.8
	Combined	300	90.2	2.6	2.9
Level III (111-150)	1	100	116.8	3.2	2.8
	2	100	116.9	3.2	2.8
	3	100	117.3	2.9	2.5
	Combined	300	117.0	3.1	2.7
Level IV (151-250)	1	100	193.0	4.8	2.5
	2	100	192.4	4.6	2.4
	3	100	192.1	4.0	2.1
	Combined	300	192.5	4.5	2.3
Level V (251-400)	1	100	315.6	6.3	2.0
	2	100	314.2	6.2	2.0
	3	100	315.0	6.0	1.9
	Combined	300	314.9	6.2	2.0

2. Linearity:

Linearity was evaluated using 10 levels of venous whole blood glucose concentrations (24.9, 40.3, 80.3, 149.8, 249.0, 340.0, 409.5, 508.8, 580.3 and 620.8 mg/dL) as determined by the comparator method YSI 2300. Each glucose level was measured in replicates of 10 using 10 glucose meters and 3 lots of test strips, and the values from the Bioland Blood Glucose Monitoring System were compared to the values obtained from the comparator method, YSI 2300. Linear regression analysis of the results yielded the following results:

Test strip lot 1:	$y = 0.9934 x + 2.1362$	$R^2 = 0.9997$
Test strip lot 2:	$y = 1.0042 x + 0.0776$	$R^2 = 0.9996$
Test strip lot 3:	$y = 1.0007 x - 0.0366$	$R^2 = 0.9999$

The results of the linearity study support the sponsor's claimed glucose measurement range of 40- 600 mg/dL. If a sample is less than 40 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample exceeds 600 mg/dL glucose, the result is flagged by the meter as "Hi". The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

To assess potential interferences, a study was conducted using venous whole blood samples adjusted to three glucose levels, as measured by the comparator method, YSI 2300: 50-70, 110-130 and 225-270 mg/dL. Each of these samples was divided into a test pool and a control pool, with each of the potential endogenous and exogenous interfering substances added to the test pool. The sponsor tested 24 exogenous and endogenous substances. The study was conducted using 3 lots of test strips and 10 meters, for a total of 30 replicates per test sample. The difference between test sample and control sample meter results was calculated. The table below shows the highest concentration of substance tested at which no significant interference (as defined by the sponsor as ± 10 mg/dL for glucose concentrations < 100 mg/dL and ± 10% for glucose concentrations > 100 mg/dL) was observed:

Potential Interfering Substance	**Highest Concentration Without Significant Interference (mg/dL)**
Acetaminophen	8.0
Ascorbic Acid	5.0
Unconjugated Bilirubin	90
Cholesterol	500
Creatinine	5.0
Dopamine	2.0
EDTA	360
Galactose	900
Gentisic Acid	5.0
Reduced Glutathione	53
Hemoglobin	500
Heparin	8000 U/dL
Ibuprofen	50

Potential Interfering Substance	Highest Concentration Without Significant Interference (mg/dL)
Icodextrin	13
L-Dopa	10
Maltose	900
Mannitol	3.0
Methyldopa	25
Salicylic Acid	60
Tolazamide	100
Tolbutamide	400
Triglycerides	2000
Uric Acid	8.0
Xylose	100

The sponsor included the following statements in the labeling:

- Acetaminophen in your blood (> 8.0 mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you have a disease or condition that elevates your blood uric acid level (> 8.0 mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.

4. Assay Reportable Range:

The reportable range is 40 - 600 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Bioland Blood Glucose Monitoring System is traceable to the NIST (SRM) 917A glucose reference material. A method comparison was performed using the candidate device and YSI 2300 as the comparator method.

Test Strip Stability

Test strip stability was assessed using real-time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a shelf life stability of 24 months and an open vial stability of 90 days at the recommended storage conditions of 39.2-104 °F (4-40°C) and relative humidity (RH) of 10%-85%.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See lay user study below in section C3.

2. Matrix Comparison:

   Not applicable. The device is only intended for use with fresh capillary whole blood from a fingerstick.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   To assess the performance of Bioland Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 351 lay-user participants. The users were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test according to the instructions and training materials routinely provided with the system. A total of 100 Bioland meters and 3 lots of Bioland test strips were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the Bioland Test System against results obtained with the laboratory-based comparator method (YSI 2300 glucose analyzer). The glucose concentrations in the samples ranged between 50.7 - 384 mg/dL, as measured by the YSI 2300. The set included 57 native samples with glucose concentration < 80 mg/dL and 16 samples with glucose concentration > 250 mg/dL. The results obtained with the candidate device were compared to the results obtained with the comparator method, YSI 2300, and are summarized below:

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
26/40 (65.00%)	38/40 (95.00%)	40/40 (100.00%)	40/40 (100.00%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
154/311 (44.52%)	260/311 (83.60%)	308/311 (99.04%)	311/311 (100.00%)

Combined glucose concentrations across the entire measuring range:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
173/351 (49.29%)	293/351 (83.48%)	346/351 (98.58%)	351/351 (100.0%)

Results of the linear regression analysis:

Slope	Y-intercept	R^2
1.0289	-1.7316	0.9716

A Flesch-Kincaid readability assessment was conducted, and the results demonstrate that the Meter Manual and Test Strip Insert were written at an 8th grade level or less.

The study participants answered questions in two questionnaires for the investigator to evaluate their understanding of the system after participating in the lay-user study. The results demonstrated that the participants were able to understand the labeling and conduct the testing on their own.

Accuracy at extreme glucose values:

To further assess the performance of the Bioland Blood Glucose Monitoring System at the extreme upper and lower ends of the claimed measuring range, the sponsor altered 444 capillary whole blood samples, by spiking or allowing samples to glycolyze, to achieve glucose concentrations below 80 mg/dL (216 samples; 32.1 – 79.9 mg/dL according to YSI 2300) and above 250 mg/dL (250 samples; 254.5 – 598.0 mg/dL according to YSI 2300). Results obtained with the candidate device using three test strip lots and were compared the results obtained with the comparator method, YSI 2300. The results are summarized below:

Glucose concentrations < 80 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
94/194 (48.45%)	159/194 (81.96%)	187/194 (96.39%)	193/194 (99.48%)

Glucose concentrations > 250 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
141/250 (56.40%)	212/250 (84.80%)	249/250 (99.60%)	250/250 (100.00%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The labeling includes the following expected glucose values for people without diabetes:

Time of day	People without diabetes
Before breakfast (fasting)	< 100 mg/dL
Two hours after meals	< 140 mg/dL

Source: American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43.

F Other Supportive Instrument Performance Characteristics Data:

1) Hematocrit Study:
The Bioland Blood Glucose Meter System was assessed at 20%, 25%, 30%, 35%, 40%, 45% 50%, 55% and 60% hematocrit levels, and at 5 glucose concentrations (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL). Each sample was tested in replicates of 10 using 10 meters and 3 lots of test strips, for a total of 30 replicates per sample. The values were compared with the glucose measurements obtained from YSI 2300 comparator method. The % bias of the Bioland Blood Glucose Monitoring System relative to YSI 2300 demonstrated adequate performance to support the claimed hematocrit range of 20-60%.

2) Altitude study:
To assess the effect of altitude, venous whole blood samples adjusted to 5 glucose concentrations covering the measuring range (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL) were tested at elevations of 298, 4790 and 10744 feet above sea level (0 feet) in replicates of 10, using 10 meters and 3 lot of test strips, for a total of 30 replicates per samples). Values measured by the candidate device were compared to the comparator method YSI 2300. The results support the claim that the Bioland Blood Glucose Monitoring System can be operated at altitudes of up to 10,744 ft.

3) Operating conditions (temperature, humidity):
The Bioland Blood Glucose Monitoring System was tested at different temperature and humidity conditions to assess the effect of operation environment on the meter's performance. Temperatures ranging from 45-110°F (7.2-43.3°C) and relative humidity from 10-90% were tested. Meter results were compared to the YSI 2300 comparator

method. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. Each of 3 venous whole blood glucose levels (30-50; 111-150 and 251-400 mg/dL) were tested by 10 meters, using 3 lots of test strips, for a total of 10 replicates per sample. Values measured by the Bioland Blood Glucose Monitoring System were compared to the comparator method YSI 2300 method. The study results support the labeled operating conditions claim of 50-104°F (10-40°C) and 15-85% RH.

4) Sample volume study:
To verify the test strip minimum sample volume requirement (0.7 µL), venous whole blood samples with the following glucose concentrations levels were used: 30-50 mg/dL, 111-150 mg/dL and 251-400 mg/dL. Sample volumes of 0.6, 0.7 and 0.8 µL were tested using 10 meters and 3 lots of test strips for a total of 30 measurements per sample volume per glucose level. Values obtained with the candidate device were compared to values obtained using the comparator method (YSI 2300). When the sample volume is lower than 0.7 µL the measurement procedure will not start and the meter gives an error message. This feature was validated and was shown to function as intended. Results support the claimed minimum sample volume of 0.7 µL.

5) Flex Studies
Intermittent sampling, sample perturbation, testing with used test strips and a variety of mechanical/durability testing (i.e., vibration test, drop test) was completed by the sponsor. The testing performed demonstrated that the Bioland Blood Glucose Monitoring System is robust to these expected use scenarios.

6) EMC
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.

7) Cleaning and disinfection robustness evaluation (Infection control studies)
The device is intended for a single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory, demonstrating removal of the HBsAg antigen with the chosen disinfectant, Clorox Germicidal Wipes (EPA Registration Number 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 3,650 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfection over the 5-year single-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8) Test strip lot release criteria
The test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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