March 20, 2020

Bioland Technology Ltd.
℅ Ke-Min Jen
No. A6B7 (Block G), ShangRong Industrial Zone
No. 5 Baolong Road, Baolong Community, Longgang District,
Shenzhen, CN 518116 Guangdong

Re: K191657
Trade/Device Name: Bioland Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: June 12, 2019
Received: June 21, 2019

Dear Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191657

Device Name
Bioland Blood Glucose Monitoring System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary (Per 21 CFR 807.92)　**510(k) number:** K191657

Type of 510(k) submission	Traditional
Basis for the submission	A New Device
Common Name of the Proposed Device	Self-Monitoring Blood Glucose Test Systems
Trade name	Bioland Blood Glucose Monitoring System
510(k) submitter	Bioland Technology Ltd. No. A6B7 (Block G), ShangRong Industrial Zone No. 5 Baolong Road, Baolong Community, Longgang District 518116, Shenzhen, Guangdong, People's Republic of China Website: http://www.bioland.com.cn Email: bioland-c@bioland.com.cn Phone: +86-755-2896-1218 Fax: +86-755-2896-2868
Registered Establishment Number	3004101980
Owner number	9057599
Date prepared	March 17, 2020
Contact person	Dr. JEN, KE-MIN TEL: +886-3-5208829　FAX: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference for continued confidentiality (21 CFR 807.95)	510(k) Summary
Classification regulation	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER　(21 CFR 862.1345)
Class	2
Panel	Clinical Chemistry
Product code	NBW
Predicate Device	
Manufacturer:	Bioland Technology Ltd.
Proprietary name:	Bioland G-423 Blood Glucose Monitoring System
510(k) number:	K113077

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- **Indications 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.

- **Device Description:**

  The Bioland Blood Glucose Monitoring System (hereafter as the System) is an in vitro diagnostic device intended for the measurement of glucose in capillary blood. The System consists of the **Bioland Blood Glucose Meter, Bioland Blood Glucose Test Strips, lancing device / sterile lance**t and **Bioland Glucose Control Solution.** The Bioland Glucose Control Solution is for use with the Bioland Blood Glucose Meter and Bioland Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. These products have been designed and tested to work together as a system to produce accurate blood glucose test results. The measured result can be transferred to the appointed equipment that has been connected via the Bluetooth function.

- **Test Principle**

  Electrochemical biosensor with carbon electrodes that is referring to detection of glucose by the test strips. The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

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- **Comparison Table**

Comparison Items	Predicate device	Subject device	Verdict
Manufacturer	Bioland Technology Ltd.	Bioland Technology Ltd.	Same
Device name model number	Bioland Blood Glucose Monitoring System, G-423	Bioland Blood Glucose Monitoring System, G-427B	Similar
Product Code	NBW	NBW	Same
510(k) Number	K113077	K191657	--
Indications for Use (IFU)	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.	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
Test Principle	Electrochemical biosensor with carbon electrodes that is referring to detection of glucose by the test strips. The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.	Electrochemical biosensor with carbon electrodes that is referring to detection of glucose by the test strips. The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase on the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.	Same
Enzyme	Glucose oxidase	Glucose oxidase	Same
Measuring method	Amperometric technology using glucose oxidase	Amperometric technology using glucose oxidase	Same
Display	LCD	LCD with backlight	Similar
Specimen type	Capillary whole blood from fingertip	Capillary whole blood from Fingers	Same

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Detecting Range	20 ~ 600 mg/dL	40 ~ 600 mg/dL	Similar
Operating conditions	50°F~104°F (10 °C ~ 40 °C) Humidity <90% RH	50°F~104°F (10 °C ~ 40 °C) Humidity: 15% ~ 85%RH	Similar
Storage /Transportation condition (System: Meter & Test Strips)	39.2°F ~104°F (4 °C ~ 40 °C) Humidity <85% RH	39.2°F~104°F (4 °C ~ 40 °C) Humidity: 10% - 85% RH	Similar
Storage /Transportation condition (Meter)	-4°F~131°F (−20°C ~ 55 °C) Humidity < 93±3% RH 700hPa ~ 1060hPa	-4°F~131°F (−20°C ~ 55 °C) Humidity < 93±3% RH 700hPa ~ 1060hPa	Same
Temperature compensation mechanism	Automatic compensation with built-in thermistor	Automatic compensation with built-in thermistor	Same
Maximum operating altitude	10,744 feet	10,744 feet	Same
Test strip chemical component	10% Glucose Oxidase (A. niger) 50% Electron shuttle 8% Enzyme protector 32% Non-reactive ingredients	10% Glucose Oxidase (A. niger) 50% Electron shuttle 8% Enzyme protector 32% Non-reactive ingredients	Same
Meter Weight (w/o batteries)	54.6g	48.0 g	Different
Test strip calibration	Use code test strip to calibrate the meter	No Code function, no need to calibrate the meter	Different
Control solutions	TaiDoc Glucose Control Solution, Level 1, Level 2, Level 3, cleared under K093724	Bioland Glucose Control Solution Level 1, Level 2, Level 3	Different
Hct range	15% ~ 55%	20% ~ 60%	Different
Sample volume	≧1.8 uL	≧0.7 uL	Different
Meter dimension	81 (L) ×62 (W) x 19 (H) mm	90 (L)×54 (W)×13 (H) mm	Different
Battery power	1 x CR2032 battery (DC 3V)	DC 3V (AAA×2 alkaline batteries)	Different
Battery life	About 1000 normal tests	About 500 normal tests	Different
Measuring Time	10 sec	6 sec	Different
Memory storage	180 tests	448 tests	Different

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- **Substantial Equivalence (SE) Discussion**

A claim of substantial equivalence is made to Bioland G-423 Blood Glucose Monitoring System, K113077. Both of them have the same indications for use, the same working principle and technologies, operating & storage conditions and detecting range. The major differences for both devices are Meter weight, Test strip calibration, Control solution, Hct Range, Sample volume, Meter dimension, Battery power, Battery life, Measuring time and Memory storage.

The meter weight without batteries for the subject device is 48.0 grams and is 54.6 grams for predicate device. The subject device is lighter than the predicate device. Since they are used at home, the lighter weight of the subject device will bring more convenience for the users. The difference of weights between subject device and predicate device is related to the manufacture's design characteristics, and it will not raise any new safety and effectiveness concerns for subject device.

The predicate device uses code test strip to calibrate the meter. The subject device provides No Code function, which means that the user does not need to calibrate the meter, making it easier for the user to monitor blood glucose level at home. That also means the subject device is more convenient to use than the predicate device, and the difference will not raise any new safety and effectiveness concerns for the subject device.

The control solutions are different brands. The control solutions of the predicate device is TaiDoc Glucose Control Solution, and the subject device is Bioland Glucose Control Solution. They are all labeled the same names as Level 1/Level 2/Level 3. Though the real glucose concentrations for Levels 1/2/3 are not the same, the user can use them for quality control purposes. The differences of control solutions will not raise any new safety and effectiveness concerns for the subject device.

The Hct ranges for the subject device and predicate device are different. The Hct range for the subject device is 20% to 60% and it is 15% to 55% for predicate device. As the effect of Hct range in the blood has been tested and validated, it is indicated in the labeling. The difference of Hct range will not raise any new safety and effectiveness concerns for the subject device.

The sample volume for the subject device is 0.7 uL and it is 1.8 uL for the predicate device. Since less sample volume means more convenient to the users at home, the short volume detection testing was performed and passed. The subject device will not bring any new safety and effectiveness concerns due to the less sample volume.

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The meter dimension of the predicate device is different from the subject device. This difference is due to the different design aspects, and not related to the safety and effectiveness concerns.

The battery power is one CR2032 (DC 3V) battery for the predicate device and 2 AAA alkaline (DC 3V) batteries for the subject device. Their resultant voltages of the electrical circuits are the same DC 3V, and the differences of battery types are related to the different electrical circuit design aspects, not related to the safety and effectiveness concerns. The batteries passed the electrical safety testing of IEC 61010-1:2010 and IEC 61010-2-101:2015 and the relevant bench performance testing, so there is no new safety and effectiveness concerns raised by the difference of batteries used.

The battery life is 500 measurements for the subject device and it is 1000 measurements for the predicate device. This is the direct result due to using the different batteries types. There is no new safely and effectiveness concerns raised by the different batteries used.

Measurement time for the subject device is 6 seconds and it is 10 seconds for the predicate device. The user of the subject device will get the measurement data faster than the predicate device. The subject device is more convenient or safer than the predicate device. There is no any new safety and effectiveness concerns raised by different measurement times for the subject device.

Memory storage for the subject device is 448 sets and it is 180 sets for the predicate device. Since the more memory storage means more space for storing the measurement data for the user's' reference. The difference of memory storages will not raise any new safety and effectiveness concerns for the subject device.

Besides, the subject device and the predicate device are intended for use in the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The subject device complies with the *IEC/EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements* and the *IEC/EN 61010-2-101 2015 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*. Thus, the differences listed above will not raise any new safety and effectiveness concerns for the subject device. The subject device is substantially equivalent to the predicate device K113077.

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Synopsis of Test Methods and Results

Pre-clinical data are employed upon submission of this 510(k) premarket notification according to the *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, issued on October 11, 2016*.

- **Summary of performance testing**

  - **Altitude study:**

    The testing results show the individual bias is less than ±10 % compared with the mean value of Glucose Analyzer YSI 2300 from altitude 298 feet (91 m) to 10,744 feet (3,275 m). The SD at blood glucose concentration < 100 mg/dL and CV at the blood glucose concentration ≥ 100 mg/dL for the measurements were less than 5.0 mg/dL and 5.0 %, respectively. The testing results met the acceptance criteria. It shows no significant altitude effects on the blood glucose measurement of the Bioland Blood Glucose Monitoring System G-427B from altitudes 298 feet to 10,744 feet (91 m to 3,275 m).

  - **Detection limit evaluation report**

    The test results show that when the sample glucose value is lower than 20 mg/dL, the Bioland blood glucose meter will display "**Lo**", and when the sample glucose value is higher than 600 mg/dL, the Bioland blood glucose meter will display "**Hi**". These test results meet the acceptance criteria. The BGMS G-427B passes the detection limit evaluation.

  - **Hematocrit interference study:**

    According to the test results, the mean differences of the BGMS G-427B measurements fall within **± 10 mg/dL** at glucose concentration < 100 mg/dL, and within **±10%** at glucose concentration ≥ 100 mg/dL from Hct 20 % to Hct 60 %. All of SD and CV were within 5.0 mg/dL and 5.0% in this study respectively. The test results met the acceptance criteria. The Hct ranges from **20% to 60%** were available for Bioland Blood Glucose Monitoring System G-427B.

  - **Interference substances evaluation:**

    This evaluation was conducted under the directions of FDA Guideline "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on October 11, 2016 and CLSI EP7-A2. According to this study, evaluating 24 endogenous and exogenous substances in venous blood samples with 5 different levels of glucose concentrations, split into a control sample and a test sample.

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The % difference between the test and control sample was calculated. The highest concentration tested at which no significant interference was summarized as below.

A sample with large amount of reducing substances such as Acetaminophen (≦ 8.0 mg/dL), Ascorbic Acid (≦5.0 mg/dL), Bilirubin (≦90 mg/dL), Cholesterol (≦500 mg/dL), Creatinine (≦5.0 mg/dL), Dopamine (≦2.0 mg/dL), EDTA (≦ 360 mg/dL), Galactose (≦900 mg/dL), Gentisic acid (≦5.0 mg/dL), Glutathione (≦53 mg/dL), Hemoglobin (≦500 mg/dL), Heparin (≦8000 U/dL), Ibuprofen (≦50 mg/dL), Icodextrin (≦13 mg/dL), L-dopa (≦10 mg/dL), Maltose (≦900 mg/dL), Methyldopa (≦3.0 mg/dL), Pralidoxime Iodide (≤25 mg/dL), Salicylate (≤60 mg/dL), Tolazamide (≤100 mg/dL), Tolbutamide (≤ 400 mg/dL), Triglycerides (≤ 2000 mg/dL), Uric Acid(≤ 8.0 mg/dL), Xylose (≤100 mg/dL).

■ **Linearity evaluation:**

Linearity evaluation are conducted under the directions of **CLSI EP6-A**. According to our test results, the correlation coefficient r = 0.9998, which is greater than 0.95, that is to say, the device G-427B and YSI 2300 were highly correlated. The linearity of our measurement is acceptable between 40 to 600 mg/dL. 100 % of the bias of individual glucose results fall within ±10% or ±10 mg/dL. The test results met the acceptance criteria. The Bioland Blood Glucose Monitoring System G-427B passes the linearity testing.

■ **Precision testing:**

There are two parts, within-run and within-day testing, for the precision testing. The evaluation was conducted according to the FDA Guideline "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on October 11, 2016. The precision evaluation results of Bioland Blood Glucose Monitoring System G-427B meet the acceptance criteria, i.e., **CV within 5%** at glucose concentration ≧ 100 mg/dL and **SD within 5 mg/dL** at glucose concentration < 100 mg/dL. The summary tables of within–run and within-day precision testing are shown as below. The test results meet the acceptance criteria, and Bioland Blood Glucose Monitoring System G-427B passes the precision evaluation.

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Summary table of within-run precision testing with venous whole blood samples

Glucose concentration interval (mg/dL)		30-50	51-110	111-150	151-250	251-400
YSI Mean(mg/dL)		40.3	89.9	131.5	199.3	323.8
	Mean (mg/dL)	40.0	89.7	130.8	200.0	322.1
Lot1	SD	2.7	3.1	4.6	7.2	11.1
	CV(%)	6.6%	3.5%	3.5%	3.6%	3.4%
	Mean (mg/dL)	40.2	90.2	130.0	199.9	323.2
Lot2	SD	2.7	3.1	4.7	6.5	10.9
	CV(%)	6.7%	3.5%	3.6%	3.3%	3.4%
	Mean (mg/dL)	40.0	89.9	130.7	201.3	320.9
Lot3	SD	2.5	3.1	4.6	7.0	10.1
	CV(%)	6.3%	3.4%	3.5%	3.5%	3.1%
	Mean (mg/dL)	40.1	89.9	130.5	200.4	322.1
Pooled	SD	2.6	3.1	4.6	6.9	10.7
	CV(%)	6.5%	3.5%	3.6%	3.4%	3.3%

Summary table of within-day precision testing with control solutions

Glucose concentration interval (mg/dL)		30-50	51-110	111-150	151-250	251-400
YSI Mean(mg/dL)		41.9	94.0	131.1	199.2	325.3
	Mean (mg/dL)	40.1	90.5	130.8	193.0	315.6
Lot1	SD	2.0	2.5	4.6	4.8	6.2
	CV(%)	5.1%	2.8%	3.5%	2.5%	2.0%
	Mean (mg/dL)	40.1	90.3	130.0	192.4	314.2
Lot2	SD	2.0	2.7	4.7	4.6	6.2
	CV(%)	5.1%	3.0%	3.6%	2.4%	2.0%
	Mean (mg/dL)	40.0	89.8	130.7	192.1	315.0
Lot3	SD	1.9	2.5	4.6	4.0	6.0
	CV(%)	4.9%	2.8%	3.5%	2.1%	1.9%
	Mean (mg/dL)	40.1	90.2	130.5	192.5	314.9
Pooled	SD	2.0	2.6	4.6	4.5	6.2
	CV(%)	5.0%	2.9%	3.6%	2.3%	2.0%

■ **Robustness validation test:**

This validation test was conducted under the directions of FDA Guideline "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on October 11, 2016 and ISO 15197:2013. According to the test results, the appearance and structures of the meters were normal after 3,650 cycles of cleaning and disinfection. Also, based on the results of the accuracy test, all the individual

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bias of the test results compared with YSI mean were less than ±10 mg/dL at glucose concentrations < 75 mg/dL and less than ± 10 % at glucose concentrations ≥ 75 mg/dL. The test results meet the acceptance criteria. The Bioland Blood Glucose Monitoring System passes the Robustness validation study.

■ **Short volume detection testing:**

Under the directions **CLSI EP7-A2** and FDA Guideline *"Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use" issued on October 11, 2016*. The test results met the acceptance criteria by applying the blood volume ≥ 0.7μL. The volume of blood sample required at least 0.7μL for Bioland Blood Glucose Monitoring System G-427B. If the blood volume is not enough, the device will detect this shortage situation, and the **5-second countdown procedure is not to start.**

■ **System operation conditions testing**

The study was performed in accordance with guidelines of *ISO 23640:2011 In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents*. According to the test results, the bias or bias % was less than 10 mg/dL or 10% and CV/SD were less than 5.0% / 5.0 mg/dL. The test results met the acceptance criteria. So we can acclaim that the system operating conditions for the subject device are 50 ºF – 104 ºF, 15% - 85% RH.

■ **Equipment temperature exposure limits for storage testing**

The study was performed in accordance with guideline of *EN ISO 15197:2015, Section 5.11: Equipment temperature exposure limits for storage*. According to the test results, the function and repeatability of the meters after being treated to extreme temperature, -4 ºF or 131 ºF fall within the acceptance criteria. That is, the meters could stand the extreme temperature (-4 ºF to 131 ºF), as required in EN ISO 15197:2015.

■ **Equipment humidity exposure limits for storage testing**

The study was performed in accordance with guideline of *EN ISO 15197:2015, Section 5.12: Equipment humidity exposure limits for storage*. According to the test results, the function and repeatability of the meters after being treated to extreme humidity, 93±3.0% RH at 89.6 ºF, fall within the acceptance criteria. That is, the meters could stand the extreme humidity (93±3% RH, 89.6 ºF) as required in EN ISO 15197:2015.

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■ **Vibration and Shock Test**

The study was performed in accordance with guideline of IEC 60068-2-64:2008, IEC 61010-1:2010 and EN ISO 15197:2015, Section 5.10: *Mechanical resistance to vibration and shock.* According to the test results, the function and repeatability after vibration and drop tests fall within the acceptance criteria. That is, the meters could stand the vibration and drop tests required in EN ISO 15197:2015, IEC 60068-2-64:2008 and IEC 61010-1:2010.

■ **Shelf life evaluation:**

The study was performed in accordance with guidelines of ISO 23640:2011. Two components were evaluated respectively for Bioland Blood Glucose Test Strips and Bioland Glucose Control Solutions. There are two cases to conduct for each component. One case is to evaluate the stability of first opening vial in real-time study and another case is shelf life evaluation for unopened vial in real-time study. According to the test results, the unopened vials of the Bioland Blood Glucose Test Strips were stable for **24 months** and **90 days** for in-use (opened) vials. The unopened vials of the Bioland Glucose Control Solutions were stable for **12 months** and **90 days** for in-use (opened) vials.

■ **Sample perturbation study:**

Sample perturbation occurs when a user has applied an appropriate volume of blood to the test strip for glucose measurement but an event such as wicking of blood away from the test strip, flicking of the test strip or flicking of the meter occurs during the start of measurement. Under the FDA Guideline "*Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use"* issued on October 11, 2016 and CLSI EP7-A2, the results show the sampling perturbation has no significant effect on precise blood glucose measurement for Bioland Blood Glucose Monitoring System.

■ **Testing with used strips:**

Under the directions of FDA Guideline "*Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use*" issued on October 11, 2016, the test results showed when the Bioland Blood Glucose Monitoring System is tested with a used test strip, the System will not provide any measurement data, and the 5-second countdown will not activate.

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■ **User performance study (Lay user study):**

This User performance study was conducted under the directions of FDA Guideline "*Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use*" issued on October 11, 2016. After a certain period of reading user manual, the Bioland Blood Glucose Monitoring System G-427B can be operated properly by a lay user. The test results show that the populations of individual bias ±15% for glucose concentration across the entire range are over 95%. The test results meet the acceptance criteria. We claim that the Bioland Blood Glucose Monitoring System can be operated properly by lay users even in the case of the absence of any guidance.

Summary of data within specified mg/dL of the comparator method for glucose concentrations across the entire range:

Within ±5%	Within ±10%	Within ±15%	Within ±20%
173/351 (49.29%)	293/351 (83.48%)	346/351 (98.58%)	351/351 (100%)

■ **Satisfaction evaluation**

More than 85% of volunteers agree that the labels on the packing and the user manual provided enough information of the product for the readers. More than 95 % of volunteers' score were higher than 80 points. It indicates that the written materials could provide enough information of the product for the lay users, so they can comprehend the contents easily even without the explanation from the professionals.

■ **Usability engineering file:**

This usability engineering file is prepared in accordance with EN 60601-1-6: 2010 (IEC 60601-1-6: 2010) and EN 62366: 2008 (IEC 62366: 2007). It contains the records/documents generated for usability engineering process activities. After reviewing the records of usability validation activities, evidence shows that there is no usability problem when validated under normal condition and the worst case scenarios.

■ Virucidal efficacy against Hepatitis B surface Antigen (HBsAg) by the Clorox Germicidal Wipes disinfectant is conducted on the following parts:

- On main housing materials of ABS,
- On test slot (port) of PMMA (transparent), and
- On LCD display lens of PC (transparent).

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The results passed the acceptance criteria for three parts of the subject device.

- **Conclusions**

The conclusions drawn from the non-clinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.