August 12, 2022

Bioland Technology Ltd.
Eric Tan
Regulatory manager
No. A6B7 (Block G), ShangRong Industrial Zone, No. 5 Baolong
Longgang District
Shenzhen, Guangdong 518116
China

Re: K202739
Trade/Device Name: Bioland G-425-2V Blood Glucose Monitoring System
Bioland G-425-2 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 16, 2022
Received: May 16, 2022

Dear Eric Tan:

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,

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202739

Device Name
Bioland G-425-2V Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Bioland G-425-2V Blood Glucose Monitoring System is comprised of Bioland G-425-2V blood glucose meter and Bioland Blood Glucose Test Strips.
The Bioland G-425-2V 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 G-425-2V 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 G-425-2V Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Bioland G-425-2V 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202739

Device Name
Bioland G-425-2 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Bioland G-425-2 Blood Glucose Monitoring System is comprised of Bioland G-425-2 blood glucose meter and Bioland Blood Glucose Test Strips.
The Bioland G-425-2 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 G-425-2 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 G-425-2 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Bioland G-425-2 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)

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510(k) Summary K202739

1. Applicant

Name: Bioland Technology Ltd.

Address: No. A6B7 (Block G) Shangrong Industrial.Zone, No.5 Baolong Road, Baolong Community Longgang District, 518116 Shenzhen, Guangdong PEOPLE'S REPUBLIC OF CHINA

Tel: +86 755 3690 0999

Fax: +86 755 3329 6299

Contact person: Eric Tan

E-mail: regulator-b@bioland.com.cn

The date of summary was prepared: 2021.12.30

2. Subject device

Trade name: Bioland G-425-2V Blood Glucose Monitoring System

Bioland G-425-2 Blood Glucose Monitoring System

Classification name: System, Test, Blood Glucose, Over the Counter

Regulation Medical Specialty: Clinical Chemistry

Product Code: NBW

Regulation number: 862.1345

Device class: II

Code of Federal Regulations: 21CFR 862.1345

3. Predicate Device

Device name: Bioland Blood Glucose Monitoring System

K number: K191657

Manufacturer: Bioland Technology Ltd.

4. Indication for use

4.1 Bioland G-425-2V Blood Glucose Monitoring System

The Bioland G-425-2V Blood Glucose Monitoring System is comprised of Bioland G-425-2V Blood Glucose Meter and Bioland Blood Glucose Test Strips.

The Bioland G-425-2V 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 G-425-2V 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 G-425-2V Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Bioland G-425-2V Blood Glucose Monitoring System is not for use in neonates.

4.2 Bioland G-425-2 Blood Glucose Monitoring System

The Bioland G-425-2 Blood Glucose Monitoring System is comprised of Bioland G-425-2 Blood Glucose Meter and Bioland Blood Glucose Test Strips.

The Bioland G-425-2 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 G-425-2 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 G-425-2 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Bioland G-425-2 Blood Glucose Monitoring System is not for use in neonates.

5. Device Description

The Bioland G-425-2V Blood Glucose Monitoring System consists of three main components: the meter (with voice feature , no Bluetooth features), test strip and control solutions. Bioland Blood Glucose Test Strips (Test strips are the same as k191657) and Bioland Glucose Control Solution (Control solution are the same as K191657) can be used with the Bioand G-425-2V Blood Glucose Monitoring System.

The Bioland G-425-2 Blood Glucose Monitoring System consists of three main components: the meter (No voice feature, no Bluetooth features), test strip and control solutions. Bioland Blood Glucose Test Strips (Test strips are the same as k191657) and Bioland Control Solution (Control solution are the same as k191657) can be used with the Bioland G-425-2 Blood Glucose Monitoring System.

The Bioland G-425-2V / G-425-2 Blood Glucose Monitoring System consists of:

a) Bioland G-425-2V / G-425-2 Blood Glucose Meter;
b) Bioland Blood Glucose Test Strips;
c) Bioland Glucose Control Solution;

6. Principle of Operation

The Bioland G-425-2V Blood Glucose Monitoring System and Bioland G-425-2 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.

7. Substantial Equivalence table

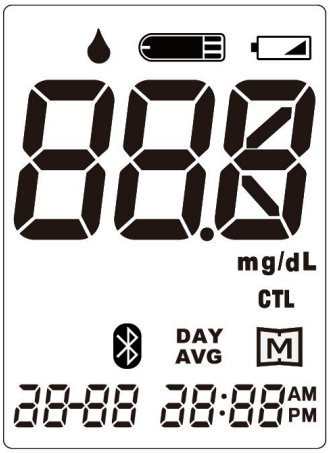
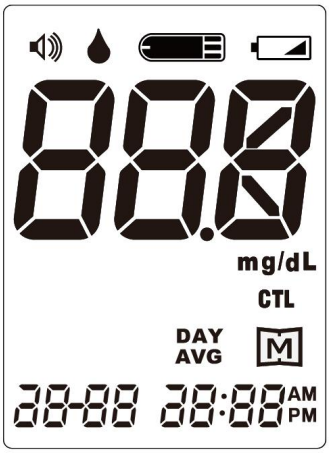
7.1 Bioland G-425-2V Blood Glucose Monitoring System

Similarities

Item	Predicate Device	Subject Device
	Bioland Glucose Monitoring System	Bioland G-425-2V Glucose Monitoring System
Intended 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	
Enzyme	Glucose oxidase	
Test Principle	Amperometric glucose biosensor	
Specimen Type	Capillary whole blood from fingertip	
Detecting Range	40~600 mg/dL	
Measurement Unit	mg/dL	
Hematocrit Range	20%~60%	
Sample Volume	⩾0.7uL	
Test strip calibration	No code function, no need to calibrate the meter	
Operating Range	50~104°F (10~40°C), 15~85%RH	
Measuring Time	6s	
Memory	448 Memories with date/time	
Power	“AAA” *2 Batteries	
Meter Size	90mm*54mm*13mm	
Weight	48.0g (Excluding batteries)	

External view	
Measurement mode	Test mode and control solution mode

Differences

Item	Predicate Device	Subject Device
	Bioland Glucose Monitoring System	**Bioland G-425-2V Glucose Monitoring System**
Bluetooth	Yes	No
Voice	No	Yes
Interface display		

In comparison with the predicate device, the modifications of the subject device are as below:

1. Trade name

   Change the trade name from Bioland Blood Glucose Monitoring System to Bioland G-425-2V Blood Glucose Monitoring System in labeling;

2. Bluetooth Function

   Remove the Bluetooth function from the predicate device, both hardware and software have changed; The hardware changes are reflected in the removal of Bluetooth module and its supply circuit, but the product structure and the overall layout of PCB has not changed. The software changes remove the Bluetooth related software codes, and the glucose algorithm

and other software functions remain unchanged.

3. Voice function

   Add the voice function from the predicate device. For the G-425-2V blood glucose meter, it broadcasts measurement value after completing measurement. Both hardware and software have changed, the hardware changes increase the horn, voice IC and its supply circuit, but the product structure and the overall layout of PCB does not change. The software change added the software code related to voice function, but the glucose algorithm and other software functions did not change.

4. Interface display

   Delete the icon "  ", add the icon "  ", it is a change in the software.

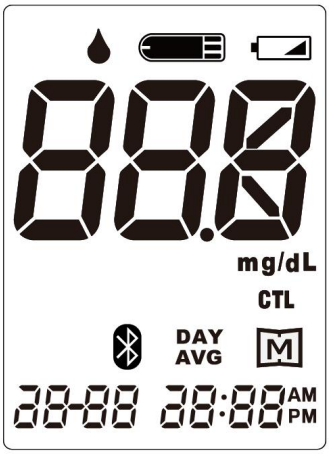
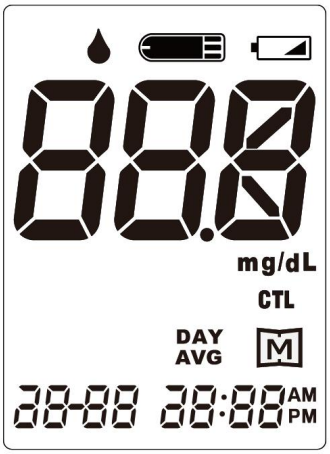
7.2 Bioland G-425-2 Blood Glucose Monitoring System

Similarities

Item	Predicate Device	Subject Device
	Bioland Glucose Monitoring System	Bioland G-425-2 Glucose Monitoring System
Intended 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	
Enzyme	Glucose oxidase	
Test Principle	Amperometric glucose biosensor	
Specimen Type	Capillary whole blood from fingertip	
Detecting Range	40~600 mg/dL	
Measurement Unit	mg/dL	
Hematocrit Range	20%~60%	
Sample Volume	⩾0.7uL	
Test strip calibration	No code function, no need to calibrate the meter	
Operating Range	50~104°F (10~40°C), 15~85%RH	
Measuring Time	6s	
Memory	448 Memories with date/time	
Power	"AAA" *2 Batteries	
Meter Size	90mm*54mm*13mm	
Weight	48.0g (Excluding batteries)	

External view	
Measurement mode	Test mode and control solution mode

Differences

Item	Predicate Device	Subject Device
	Bioland Glucose Monitoring System	Bioland G-425-2 Glucose Monitoring System
Bluetooth	Yes	No
Interface display		

In comparison with the predicate device, the modifications of the proposed device are as below:

1. Trade name

   Change the trade name from Bioland Blood Glucose Monitoring System to Bioland G-425-2 Blood Glucose Monitoring System in labeling;

2. Bluetooth Function

   Remove the Bluetooth function from the predicate device, both hardware and software have changed; The hardware changes are reflected in the removal of Bluetooth module and its supply circuit, but the product structure and overall layout of PCB has not changed. The software changes remove the Bluetooth related software codes, and the glucose algorithm and other software functions remain unchanged.

3. Interface display

Delete the icon ”  ”, it is a change in the software.

8. Summary of Design Control Activities

Based on the modifications, the risk analysis was assessed, and the risks were identified and controlled with verifications and validation activities which mitigated the risk index to acceptability. The risk analysis and design control activities were summarized below:

8.1 Risk Analysis

The risk analysis was conducted according to ISO 14971: 2019 Standard. A Failure Modes and Effects Analysis (FMEA) were assessed to identify potential hazard and unaccepted risks for each modification, The control measures were to mitigate these risks to acceptable level with the implemented verification and validation activities. The complete analysis was in risk management report in this submission.

8.2 Verification and Validation activities

The verification and validation (V&V) activities were conducted based on the impact of the modification and detailed in the risk management report. All test results met acceptance criteria and are included in the software validation report.

9. Conclusion

The Bioland G-425-2V Blood Glucose Monitoring System and Bioland G-425-2 Blood Glucose Monitoring System are substantially equivalent to the predicate device (K191657), Bioland Blood Glucose Monitoring System.