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

A. 510(k) Number:

k163087

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric assay (Glucose oxidase)

E. Applicant:

iXensor Company Ltd.

F. Proprietary and Established Names:

PixoTest 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, System Test, Blood Glucose, Over the Counter
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use, below.

2. Indication(s) for use:

   The PixoTest Blood Glucose Monitoring System is comprised of PixoTest Glucose Test Strip, PixoTest Uni-Clip, and the PixoHealth App as the display component of the system.

   The PixoTest Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip.

   The PixoTest 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 system is intended for single person use only and should not be shared. It is not intended for use in the diagnosis of or screening for diabetes and is not intended for use on neonates.

3. Special conditions for use statement(s):

   - All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. Your smartphone may also be considered biohazardous due to the presence of blood.
   - This system is not for screening for or diagnosis of diabetes mellitus.
   - Inaccurate results may occur if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
   - This system is not for use on critically ill patients.
   - Alternative Site Testing (AST) testing was not evaluated in this device.
   - Do no use at altitudes greater than 9843 ft.
   - The meter does not work in sunlight. It will not return results and cannot be used under sunlight, indirect sunlight, in the shade, or next to the window with direct sunlight. You should not purchase this meter if you will need to use it in these conditions. Do not perform the test if you are unable to read your iPhone
   - Not for neonatal use.
   - Abnormally low hematocrit levels below (<20%) may produce falsely high readings and abnormally high hematocrit (>60%) may produce false low readings. If you do not know your hematocrit level please consult your healthcare professional.
   - The battery life needs to be over 30% before using the PixoTest BGMS. If the battery is below 30%, an error will appear and the glucose measurement test cannot be started.
   - This device is not intended for use in healthcare of assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been

cleared by the 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.

- For in vitro diagnostic use only.
- For over-the-counter use and single-patient use only
- PixoTest Glucose Test Strip is for single use; it should be used once only.
- Due to the risk of spreading blood born infections, clean phone after every blood test.
- The components of this system are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.

4. Special instrument requirements:
   iPhone models 5, 5S, 6, 6S
   PixoTest Glucose Test Strip

I. Device Description:

The iXensor PixoTest BGMS consists of the following devices:

1) PixoTest Glucose Test Strip with Integrated Lancet Cartridge (single-use)
2) PixoTest Control Solutions (2 levels – 1 and 2)
3) PixoTest Standard Card
4) PixoTest Uni-Clip
5) PixoHealth App
6) Requires compatible smartphone (iPhone 5/5S/6/6S)

iXensor provides the following kits:

1) Starter (5 Pcs) Kit– includes PixoTest Standard Card, PixoTest Uni-Clip, and 5 Pcs PixoTest Glucose
2) 10 Pcs Kit – includes PixoTest Standard Card and 10 Pcs PixoTest Glucose

The iXensor PixoTest Blood Glucose Monitoring system is comprised of a test strip with an integrated lancing device, that is attached to a clip (the uni-clip accessory) that holds the cartridge over the camera of a mobile device (iPhone 5, 5S, 6, or 6S). Blood glucose is measured using the hardware camera on the iPhone 5, 5S, 6, or 6S in conjunction with the PixoTest Glucose Test Strip with Integrated Lancet Cartridge and PixoTest Uni-Clip. A plastic clip holds the test cartridge over the camera lens. A drop of fresh capillary blood is added to the test strip where a line forms in response to glucose in the blood on the test strip. A photograph is taken of the color change on the test strip and an iOS application uses the properties of the line to generate a blood glucose concentration. The PixoTest Control Solutions and PixoTest Standard Card are used to verify that the camera on the phone is operating properly.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Roche Diagnostics Corporations Accu-Chek Active System

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

   k021827

3. Comparison with predicate:

Similarities & Differences		
Item	Device iXensor PixoTest BGMS for the iPhone 5, 5S, 6, and 6S	Predicate Roche Accu-Chek Active System (k021827)
Indications for Use	For the quantitative measurement of glucose in capillary whole blood as an aid to monitor the effectiveness of diabetes control by people with diabetes	Same
Test Principle	Reflectance photometry	Same
Sample Type	Capillary whole blood from the fingertip	Capillary whole blood
Sample Volume	1.8 µL	1-2 µL
Alternative Site Testing	N/A	Forearm, calf, thigh, upper arm, palm
Measuring Range	40-500 mg/dL	10-600 mg/dL
Measuring Time	8 seconds	5 seconds
Hematocrit	20-60%	30-55%
Control Solution	2 Levels; 1 and 2	2 Levels; Low and High
Test Strip Reagent	Glucose Oxidase	Glucose Dehydrogenase
Compatible Device/OS	iPhone 5/5S/6/6S; iOS 8 or above	N/A, Meter

Similarities & Differences		
Item	Device iXensor PixoTest BGMS for the iPhone 5, 5S, 6, and 6S	Predicate Roche Accu-Chek Active System (k021827)
Power Supply	iPhone 5/5S6/6S: Built-in rechargeable lithium-ion battery	Meter: 1 type CR 2032 or equivalent lithium battery
Battery Life	N/A	1000 tests
Memory Capacity	1000 blood glucose test results with date and time	200 blood glucose test results with date and time
Coding Procedure	Code Key	Same

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

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

EN 62304:2006/AC:2008 Medical device software - Software life-cycle

L. Test Principle:

iXensor PixoTest BGMS is a device that utilizes smartphone technology in conjunction with reflectance photometry and glucose-oxidase chemical reaction testing principles to measure the glucose level in human blood. A small drop of blood is applied to the eyelet on top of the disposable PixoTest Glucose test strip with integrated lancet cartridge. The blood sample is then transferred to and absorbed by the test strip's glucose-oxidase impregnated reagent pad, which reacts with the glucose to produce a color change. The intensity of the color change is proportional to the glucose concentration present in the blood sample as detected by the camera on the mobile phone by using a clip that holds the test cartridge in place for analysis. The results are displayed on a phone application that is proprietary to the iXensor products. After 8 seconds, the blood glucose measurement result is displayed on the smartphone screen.

M. Performance Characteristics (if/when applicable):

The testing described below was performed on an iPhone 5S and iPhone 6S as representative models for the iPhone 5, 5S, 6 and 6S. The sponsor provided justification and demonstrated that the components of the phones for each claimed platform were identical with respect to the performance of their device.

1. Analytical performance:

a. Precision/Reproducibility:

Within-Run (Repeatability) with iPhone 5S
Within-run precision studies were performed using venous whole blood samples with 5 concentrations of glucose (40-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Samples were tested in replicates of ten on the iPhone 5S with the Pixo System with each of three lots of test strips and 10 meters for a total of 300 tests per glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
40-50	1	46.21	2.97	6.42
	2	45.28	2.77	6.13
	3	45.43	2.91	6.41
51-110	1	81.11	3.28	4.05
	2	80.85	3.26	4.03
	3	80.86	3.15	3.90
111-150	1	127.37	4.39	3.44
	2	127.83	4.66	3.65
	3	127.2	4.91	3.86
151-250	1	185.13	6.77	3.66
	2	185.28	6.60	3.56
	3	18593	7.50	4.03
250-400	1	331.85	7.27	2.19
	2	333.28	7.54	2.26
	3	331.66	7.52	2.27

Intermediate Precision with iPhone 5S

Intermediate (between run) precision was evaluated using three levels of glucose control solutions, 3 test strip lots, and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicates for each glucose control level. Testing was performend on the iPhone 5S with the Pixo System. Results are summarized below:

Control Solution Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
40 – 60	1	55.35	2.94	5.31
	2	55.77	2.73	4.89
	3	55.33	2.67	4.82
96 – 144	1	123.14	4.49	3.65
	2	123.15	4.12	3.35
	3	123.9	4.41	3.56
280 – 420	1	397.68	10.93	2.75
	2	397.07	11.44	2.88
	3	395.46	10.84	2.74

Within-Run (Repeatability) with iPhone 6S

Within-run precision studies were performed using venous whole blood samples with 5 concentrations of glucose (40-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Samples were tested in replicates of ten on the iPhone 6S with the Pixo System with each of three lots of test strips and 10 meters for a total of 300 tests per glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
40-50	1	45.38	2.93	6.46
	2	45.66	2.96	6.48
	3	45.45	3.03	6.66
51-110	1	81.04	3.10	3.83
	2	81.12	3.33	4.1
	3	81.08	3.23	3.98
111-150	1	127.86	4.33	3.39
	2	127.95	4.94	3.86
	3	128.67	4.43	3.44
151-250	1	186.4	6.53	3.50
	2	186.31	6.61	3.55
	3	186.94	6.32	3.38
250-400	1	332.49	7.65	2.30
	2	332.86	7.41	2.22
	3	333.1	7.93	2.38

Intermediate Precision with iPhone 6S

Intermediate (between run) precision was evaluated using three levels of glucose control solutions, 3 test strip lots, and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicate for each glucose control level. Testing was performend on the iPhone 5S with the Pixo System. Results are summarized below:

Control Solution Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
40 – 60	1	55.75	2.92	5.23
	2	55.74	2.86	5.12
	3	55.22	2.78	5.03
96 – 144	1	123.38	4.53	3.68
	2	123.01	4.56	3.71
	3	123.96	4.36	3.52
280 – 420	1	397.59	11.43	2.88
	2	398.42	10.98	2.76
	3	398.33	10.42	2.62

b. Linearity/assay reportable range:

The linearity study for the PixoTest BGMS was performed using 3 compatible iPhone 5S and 3 iPhone 6s smartphones and 3 lots of PixoTest Glucose test strip cartridges (3 smartphones tested for each lot). Venous whole blood samples were prepared at 11 levels of glucose concentrations ranging from low to high level (20, 40, 60, 90, 132, 178, 224, 316, 362, 408, 500, 550 mg/dL). Test procedures were performed in 7 replicates per lot per concentration level. The results were compared to a comparator method, the YSI 2300 laboratory analyzer.

iPhone 5S

Test Trip Lot	Slope	Intercept	R^2
1	0.9973	-2.5	0.999
2	0.9917	-2.2	0.999
3	0.9983	-3.2	0.999

iPhone 6S

Test Trip Lot	Slope	Intercept	R^2
1	0.9831	-0.27	0.999
2	0.9914	-2.72	0.999
3	0.9884	-3.48	0.999

The results of the study support the claimed glucose measurement range of 40 to 500 mg/dL. If a sample result is less than 40 mg/dL the result is flagged by the meter as "LO" and if a sample result exceeds 500 mg/dL the result is flagged by the meter as "HI". The 'HI/LO' error message feature was validated to demonstrate that the feature functions as intended.

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

Traceability: The iXensor PixoTest Blood Glucose Monitoring System is traceable to the NIST SRM 917b glucose reference material.

Test Strip Stability:

Test strip stability has been evaluated through accelerated and real-time studies. The real-time studies are on going. The testing protocols and acceptance criteria were reviewed and found to be acceptable to support the claimed shelf life stability of 24 months when stored between 50 and 104 °F and 10 – 90% relative humidity.

d. *Detection limit:*

See linearity study in Section M1b above.

e. *Analytical specificity:*

The interference study for PixoTest BGMS was performed using venous blood samples with 3 glucose concentration levels (60, 20, and 250 mg/dL) and 30 potential interfering substances. Ten compatible smartphones (iPhone 5S) and 3 lots of PixoTest Glucose test strip cartridges were used to perform 10 replicates per lot and the results were compared to a comparator method, the YSI 2300 Analyzer. Testing was repeated with the iPhone 6S. The results were consistent across the two devices. The summary of the results are presented in the table below.

Potential Interferent	**Highest concentration tested at which no significant interference is observed**
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Bilirubin	25 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
Dopamine	0.1 mg/dL
EDTA	200 mg/dL
Galactose	15 mg/dL
Gentisic acid	10 mg/dL
Glutathione	92 mg/dL
Hemoglobin	20,000 mg/dL
Heparin	5 IU/ml

Potential Interferent	Highest concentration tested at which no significant interference is observed
Ibuprofen	50 mg/dL
Icodextrin	1000 mg/dL
L-Dopa	0.5 mg/dL
Maltose	1000 mg/dL
Methyldopa	1 mg/dL
Pralidoxime Iodide	20000 mg/dL
Salicylate	60 mg/dL
Sodium	414 mg/dL
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	1500 mg/dL
Uric acid	24 mg/dL
Xylose	200 mg/dL
Mannitol	0.09 mg/dL
Sorbitol	0.09 mg/dL
Xylitol	0.09 mg/dL
Lacticol	0.09 mg/dL
Isomalt	0.09 mg/dL
Maltitol	0.09 mg/dL

The following warning is added to the labeling for interference:
If you are taking vitamin C (ascorbic acid; blood concentration ≥ 3mg/dL) then the results from your meter may not be correct.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

See section M.2.c. below for the user performance study.

b. Matrix comparison:

Not applicable.

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):

To assess the accuracy of the Pixo Test Blood Glucose Monitoring System using the iPhone 5S and 6S in the hands of the intended users, in two studies, one for the iPhone 5S and one for the iPhone 6S,105 lay users tested their own fingertip capillary blood samples using the Pixo Test. Results were compared to the measurement made using a laboratory comparator method (YSI 2300 analyzer). Samples ranged in glucose concentrations from 59 to 470 mg/dL as measured by the YSI. The meter results relative to YSI are summarized below:

iPhone 5S

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
7/14 (50%)	13/14 (92.9%)	14/14 (100%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
47/91 (51.6%)	80/91 (87.9%)	87/91 (95.6%)	91/91 (100%)

iPhone 6S

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
2/4 (50%)	4/4 (100%)	4/4 (100.0%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
54/101 (53.5%)	86/101 (85.1%)	100/101 (99%)	101/101 (100%)

Readability assessment for PixoTest BGMS were performed using the Flesch-Kincaid Grade Level Score to evaluate the readability of PixoTest BGMS User Manual, Quick Start Guide, and test strip insert and demonstrated that the labeling is written at or below and 8th grade reading level.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected glucose values for persons without diabetes:

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

   These ranges were cited from the American Diabetes Association, Classification and Diagnosis of Diabetes, 2017. Diabetes Care 40 (Suppl. 1):S11-S24

N. Instrument Name:

PixoTest Uni-Clip with the PixoHealth App on the iPhone 5S or iPhone 6S

O. System Descriptions:

1. Modes of Operation:

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

   Yes ___X____ or No _____

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

   Yes ___X____ or No _____

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:
   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 from fingerstick. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   There is no calibration required by the user for the PixoTest Blood Glucose monitoring system. The meter is automatically coded when the test strip is inserted into the meter.

6. Quality Control:

   Two levels of controls are available for use with this meter. The control solutions are sold separately. The control solution range for each control level is printed on the test strip vial label. It is recommended that users check the accuracy of the meter by using the control solutions.

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

1. Electromagnetic compatibility (EMC) (radiated emissions and immunity) testing:

The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the device system was found compliant.

2. Infection Control and Robustness Studies:
The device is intended for a single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the iPhone 5S, 6S and the Uni-Clip by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes by Clorox Professional Products (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 Uni-Clip or iPhones 5S and 6S after 7665 cleaning and 7665 disinfection steps. The robustness studies were designed to simulate 7 cleaning and disinfection procedures per day over the device system's three-year use life. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

3. Hematocrit:
The hematocrit effect study for PixoTest BGMS was performed using venous blood samples: 5 hematocrit levels (20, 30, 42, 55, and 60%) with 3 glucose concentration levels (30-50, 110-120, and 395-405 mg/dL). Six PixoTest BGMS compatible smartphones (3 iPhone 5S and 3 iPhone 6S) and 3 lots of PixoTest Glucose test strip cartridgs were used. Test procedures were performed in 30 replicates per sample (10 per lot). The results were compared against the comparator method, the YSI 2300 Analyzer, and support the claimed hematocrit range of 20-60%.

4. Altitude:
The operated altitude effect study for PixoTest BGMS evaluated performance under environment factors of 4 different altitudes: 3, 3281, 6562, and 9843 feet above sea level (10, 1000, 2000 and 3000 meters) for both the iPhone 5S and iPhone 6S. Venous blood samples with 3 glucose concentration levels (40-50 mg/dL, 96-144 mg/dL and 280-420

mg/dL) were tested using 5 PixoTest BGMS compatible smartphones and 3 lots of PixoTest Glucose test strip cartridgs. Test procedures were performed in 5 replicates per smartphone. The results were compared against reference method YSI 2300 Analyzer. The results demonstrate acceptable bias relative to the reference method to support the claim in the labeling that altitudes up to 9843 feet do not significantly affect device performance.

5. **Temperature and Humidity operating conditions:**
   The operating temperature and humidity effect study for PixoTest BGMS evaluated system performance under various environment factors: 10, 25, 35, and 42 °C (50, 77, 95, 107 °F) and 10%, 50%, and 90% relative humidity. Extreme combinations were evaluated in the procedure using venous blood containing three glucose concentration levels (51, 119, 353 mg/dL) measured on the PixoTest BGMS with the iPhone 5S and iPhone 6S, and 3 lots of PixoTest Glucose test strip cartridges. The results were compared the comparator method, the YSI 2300 Analyzer. The data support the use of the device in the claimed temperature and humidity range of 50-104°F(10-40°C) and 10-90% relative humidity.

6. **Sample Volume:**
   The sample volume study for PixoTest BGMS was performed using 3 lots of test strip cartridges, venous blood samples at 3 glucose concentration levels (60, 100, 220 mg/dL) with 5 sample volumes ranging from 1.25 to 2.5 µL. An error message, "Blood Volume Insufficient" (Error 004) is displayed with less than 2 µL of blood is applied to the test strip. Test procedures were performed in 10 replicates and results were compared to the comparator method, the YSI 2300 Analyzer. The data support the sample volume claim of 1.75 µL.

7. Customer service is available Monday through Friday 9AM-5PM PST by calling 1-800-218-0929. For hours outside of operation, please contact your healthcare professional.

8. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

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.