Food and Drug Administration
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K192369

B Applicant

iXensor Co. Ltd.

C Proprietary and Established Names

PixoTest POCT System - PixoTest POCT Analyzer and PixoTest A1c Test Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCP	Class II	21 CFR 864.7470 - Glycosylated Hemoglobin Assay	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Addition of fingerstick capillary whole blood sample claim to the previously cleared PixoTest POCT System – PixoTest POCT Analyzer and PixoTest A1c Test Kit (k181915)

B Measurand:

Glycosylated hemoglobin (HbA1c)

C Type of Test:

Quantitative Immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The PixoTest POCT System, consisting of PixoTest POCT Analyzer and PixoTest A1c Test Kit, is used for the quantitative measurement of glycated hemoglobin (%HbA1c) in fingerstick capillary and venous whole blood samples. It is an in-vitro diagnostic system intended to monitor long term glycemic control in individuals previously diagnosed with diabetes mellitus.

The PixoTest POCT System is intended for clinical laboratory and Point-of-Care Professional use. It is not intended for use in the diagnosis of or screening for diabetes and is not intended for use on neonates.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- This test should not be used in monitoring daily glucose control and should not be used to replace daily home testing of urine and blood glucose levels.
- This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss.
- For professional use in clinical laboratory and point-of-care settings.
- This test is not intended for use in the diagnosis of or screening for diabetes.
- This test is not intended for use on neonates.
- For in-vitro diagnostic use only.
- If the total hemoglobin result is outside the range of 7-23g/dL, the test result could be inaccurate.
- Collect venous whole blood using K2-EDTA, lithium heparin, sodium heparin or sodium fluoride tubes only. Do not use tubes with any other anticoagulants.
- Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the PixoTest POCT System show that there is no significant interference for samples containing Hemoglobin C (≤ 36%), Hemoglobin D (≤ 41%), Hemoglobin E (≤ 28%), Hemoglobin S (≤ 40%), Hemoglobin F (≤ 19%), and Hemoglobin A2 (< 6.5%).

D Special Instrument Requirements:

PixoTest POCT Analyzer

IV Device/System Characteristics:

A Device Description:

The iXensor PixoTest POCT System consists of the following components:

1) PixoTest POCT Analyzer, including
   - PixoHealth POCT A1c App
   - USB Charger
   - USB Type C Charge Cable
   - PixoTest POCT Calibration Card
   - Instructions for Use

2) PixoTest A1c Test Kit, including
   - PixoTest A1c Test Strips
   - Spoits (to acquire 5µl blood sample by capillary action and to mix blood and buffer together) with Latex-Tablets (containing blue dyed latex micro particles conjugated to specific antibodies for detection of HbA1c)
   - Buffer Solution Tubes
   - Instructions for Use

B Principle of Operation:

The PixoTest A1c Test kit uses an anti-HbA1c antibody which is specific for the first few amino acid residues of the glycated N-terminus of the ß-chain of hemoglobin A0. When whole blood is added to the buffer solution tube and mixed with the spoit, the erythrocytes are instantly lysed to release the glycated hemoglobin (hereafter, HbA1c). When sample mixture is loaded onto the sample port of the test panel, the mixture fluid migrates along the membrane of the test panel by capillary action, and the HbA1c is then immobilized onto the anti-HbA1c antibody coated line. The amount of the blue conjugates on the anti-HbA1c line reflects the amount of HbA1c in the sample. The intensity of hemoglobin color from the desired area on the membrane of test panel is measured. Chemical and immune reaction that occurs on the test strip is measured by the optical system in PixoTest POCT Analyzer. This system measures both fractions and uses an algorithm to convert the result into the percentage HbA1c in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):

PixoTest POCT System - PixoTest POCT Analyzer and PixoTest A1c Test Kit

B Predicate 510(k) Number(s):

K181915

C Comparison with Predicate(s):

Device & Predicate Device(s):	K192369	K181915
Device Trade Name	PixoTest POCT System – PixoTest POCT Analyzer and PixoTest A1c Test Kit	Same
General Device Characteristic Similarities		
Intended Use	Quantitative determination of percent hemoglobin A1c to monitor long term glycemic control in individuals previously diagnosed with diabetes.	Same
Test principle	Immunoassay	Same
Intended use environment	Clinical laboratories and point-of-care settings	Same
Measuring range	4.0% - 15.0%	Same
Sample volume	5 µL	Same
Sample pretreatment tools	Spoit, buffer tube	Same
General Device Characteristic Differences		
Sample Type	Fingerstick capillary and venous whole blood	Venous whole blood

VI Standards/Guidance Documents Referenced:

ISO 14971:2007, Medical devices - Application of risk management to medical devices

ISO 15223-1:2016, Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run precision, intermediate precision, and reproducibility was established in k181915.

2. Linearity:

Linearity was established in k181915.
The reportable range for the PixoTest POCT System is 4.0% to 15.0% HbA1c.

3. Analytical Specificity/Interference:

Potential interference from endogenous substances, exogenous substances, hemoglobin derivatives, hemoglobin variants, and total hemoglobin was established in k181915.

The labeling contains the following limitation regarding hemoglobin variant interference:

> *Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the PixoTest POCT System show that there is no significant interference for samples containing Hemoglobin C (≤ 36%), Hemoglobin D (≤ 41%), Hemoglobin E (≤ 28%), Hemoglobin S (≤ 40%), Hemoglobin F (≤ 19%) and Hemoglobin A2 (≤ 6.5%).*

The claimed total hemoglobin range is 7 to 23 g/dL.

4. Assay Reportable Range:

The reportable range for the PixoTest POCT System is 4.0% to 15.0% HbA1c. See Linearity (section VII.A.2.) above.

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

Traceability:
The PixoTest POCT System is traceable to the International Federation of Clinical Chemistry (IFCC) reference material.

6. Detection Limit:

The claimed HbA1c measuring range of 4.0% to 15.0% for the PixoTest POCT System is based on linearity. See Linearity (section VII.A.2.) above.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted at three point of care sites with three intended use operators at each site. Fingerstick capillary whole blood samples from 158 subjects were collected and tested in singlicate with the PixoTest POCT System using one lot of PixoTest A1c Test Kits per site (three lots total). The results obtained with the PixoTest POCT System were compared to the results obtained for paired K2-EDTA anticoagulated venous blood

samples measured with the TOSOH G7 comparative method (k011434). The range of HbA1c tested was 4.8% to 13.0% as determined by the TOSOH G7 method. Results of the linear regression analysis are shown below. A usability assessment completed by all intended use operators did not reveal any difficulties with using the device.

	N	HbA1c range (%)	Intercept	Slope	R
Site 1	50	4.8 to 12.2	0.0678	0.982	0.980
Site 2	58	5.0 to 13.0	0.1400	0.987	0.991
Site 3	50	4.8 to 10.6	-0.1300	1.020	0.985
Pooled sites	158	4.8 to 13.0	0.1110	0.985	0.988

2. Matrix Comparison:

Not applicable.

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):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The American Diabetes Association (ADA) recommended a reasonable A1c goal for many non-pregnant adults is < 7 % (53 mmol/mol). Providers might reasonably suggest more stringent A1C goals (such as 6.5 % [48 mmol/mol]) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment.
Reference: American Diabetes Association. Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018 Jan; 41 Suppl. 1: S55-S64.

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.