510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(k) number is: k181915

1. Submitter Identification:

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2. Name of the Device:

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

3. Common or Usual Name: Glycosylated Hemoglobin Assay

Product Code	Classification	Regulation Section	Panel
LCP; Assay, Glycosylated Hemoglobin	Class II	21 CFR 864.7470	Hematology 81
JJE; Analyzer, Chemistry (Photometric, Discrete), for clinical use	Class I	21 CFR 862.2160	Clinical Chemistry 75

4. Device Description:

PixoTest® POCT System consists of the following devices:

1) PixoTest® POCT Analyzer
   Include:
   - PixoHealth POCT A1c App
   - USB Charger
   - USB Type C Charge Cable
   - PixoTest POCT Calibration Card

2) PixoTest® POCT A1c Test Kit
   Include:
   - A1c Test Strip
   - Spoit with Latex-Tablet
   - Buffer Solution Tube

5. Intended 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 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.

6. Predicate Device Information
PixoTest POCT Analyzer and PixoTest A1c Kit is substantially equivalent to the following device:
Name: SD A1cCare System and SD A1cCare Spoit Type Test Kit
Device Company: SD Biosensor, Inc.
510(K) Number: k140827

7. Comparison to Predicate Devices:

Specification	Subject Device – PixoTest POCT System	Predicate Device – SD A1cCare System
Similarities & Differences		
Indications for Use	The SD A1cCare System is intended for Point-of-Care Healthcare provider use to monitor long term glycemic control in people with diabetes.	The SD A1cCare System is intended for professional use to monitor long term glycemic control in people with diabetes.
Test Principle	Reflectance photometry	
Sample Type	Venous whole blood	Fingerstick capillary or venous whole blood
Sample Volume	5µL	Same
Measuring Range	4.0-15.0%	Same
Measuring Time	3 minutes	Same
Hematocrit	25-65%	Same
Maximum Altitude	3,000m (9,843 ft)	2,000m(6,560 feet)
Operating Temperature	59-90°F (15-32°C)	59-104°F (15-40°C)
Operating Humidity	10-90% relative humidity	Same
Shelf-Life	18 months	Same
Storage Temperature	34-86°F (1-30°C)	Same
Assay method	Immunoassay	Same
Interference Substances	Acetylsalicylic acid, Ascorbic acid, Acetaminophenol, Bilirubin, Caffeine, Hydroxyzine Dihydrochloride, Triglyceride, Glyburide, Ibuprofen, Dopamine	Same
Device Dimension	Meter: 181 mm (L) x 111 mm (W) x 53mm (H)	Meter: 163 x 96 x 52 (mm)
Device Weight	Meter: 314.3g	Meter: 500g

Power Supply	Meter: 5000 mAh battery, non-removable	Meter: 4x 1.5V AA Alkaline batteries or AC Adapter
Device Display	LCD	
Memory Capacity	>10000 tests results with date and time	900 tests results with date and time
Coding Procedure	Code Key	
Calibration	QR Code for associate test kit batch Calibration Card for optical functional check	Code chip with lot-specific calibration for associated Test Kits
Analyzer Quality Control	Commercial Control Solutions	Check strip for assessing optical functionality of analyzer

Statement of No Differences:
For the reasons mentioned above, it can be concluded that the PixoTest POCT Analyzer and PixoTest A1c Test Kit are substantially equivalent to the SD A1cCare System and SD A1cCare Spoit Type Test Kit in commercial distribution, with respect to indications for use and technology.

8. Technology Characteristics:

The PixoTest® POCT Analyzer use photometry to measure HbA1c. Samples from venous whole blood can be used. This whole blood sample is applied to PixoTest® A1c Test Kit, and a reaction occurs to produce a color that is read by using reflectance photometry of the reagent area. The level of color produced is proportional to the concentration.

PixoTest® POCT Analyzer on 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. PixoTest® A1c Test Kit contains the PixoTest® A1c Test Strip (nitrocellulose membrane), Spoit with latex-tablet (blue dyed latex micro particles conjugated to specific antibodies) and Buffer solution tube (hemolysis reagent). When whole blood is added to the buffer solution and is mixed with the latex-tablet, the erythrocytes are instantly lysed to release the glycated hemoglobin (hereafter, HbA1c). When the 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 measured 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 an algorithm which converts the result into the percentage HbA1c in the sample.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation tests were performed to evaluate the performance, functionality, and reliability of the PixoTest POCT Analyzer and PixoTest A1c Test Kit. The evaluations include precision, linearity and sensitivity, interference and specificity, sample volume and matrix, altitude, EMC and operation conditions.

10. Discussion of Clinical Tests Performed:

A system accuracy study was performed by comparing venous whole blood A1c values on the PixoTest POCT Analyzer and PixoTest A1c Test Kit with values on TOSOH G7 Analyzer lab instrument.

The evaluation was conducted on 120 subjects using 3 PixoTest POCT Analyzers and 3 test strip reagent lots, at 3 point-of-care sites.

The study results demonstrate that the accuracy specifications of PixoTest POCT Analyzer and PixoTest A1c Test Kit meet the acceptance criteria.

11. Conclusions:

Performance evaluations of the PixoTest POCT Analyzer and PixoTest A1c Test Kit demonstrate substantial equivalence to the predicate device, SD A1cCare System and SD A1cCare Spoit Type Test Kit.