510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K240636

B Applicant

PixCell Medical Technologies

C Proprietary and Established Names

HemoScreen Hematology Analyzer

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of the submission is to extend the analytical measurement range for platelets (PLT) and white blood cell (WBC) counts

B Type of Test:

Quantitative complete blood count with 5-part leukocyte differential: Red Blood Cells (RBC), White Blood Cells (WBC), Platelets (PLT), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Cell Hemoglobin (MCH), Mean Cell Hemoglobin Concentration (MCHC), Red Blood Cell Distribution Width (RDW), Mean Platelets Volume (MPV), Neutrophils (NEUT; #/%), Monocytes (MONO; #/%), Lymphocytes (LYMP; #/%), Eosinophils (EO; #/%) and Basophils (BASO; #/%)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The HemoScreen is a point-of-care (POC) automated hematology analyzer intended for the enumeration and classification of the following parameters in capillary and venous whole blood (K2EDTA anticoagulated): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEUT%, NEUT#, LYMP%, LYMP#, MONO%, MONO#, EO%, EO#, BASO%, and BASO#. The HemoScreen is for in vitro diagnostic use in clinical laboratories and/or POC settings for adults and children at least 2 years of age.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The HemoScreen is a point-of-care (POC), automated hematology analyzer that provides results for complete blood count (CBC) parameters and a 5-part leukocyte differential, in capillary and venous whole blood samples. The HemoScreen system is a tabletop device and is comprised of the following components: HemoScreen reader (analyzer plus software), cartridge with preloaded reagents, blood collection sampler, on-board internal quality control, and external liquid quality controls.

The cartridge module comprises reagent compartments, a microfluidic chip and a translucent measurement portion. The reagents in the cartridge enable viscoelastic focusing, lysis of RBC, and WBC staining. In addition to the cartridge, the system includes a disposable sampler, which is used to collect the blood sample and then transfer it to the cartridge.

The HemoScreen provides the following blood count parameters: red blood cells (RBC), white blood cells (WBC), platelets (PLT), hemoglobin (HGB), hematocrit (HCT), mean corpuscular (erythrocyte) volume (MCV), mean cell (erythrocyte) hemoglobin (MCH), mean cell (erythrocyte) hemoglobin concentration (MCHC), red blood cell distribution width (RDW), mean platelets volume (MPV), neutrophils (NEUT; #/%), monocytes (MONO; #/%), lymphocytes (LYMP; #/%), eosinophils (EO; #/%) and basophiles (BASO; #/%). Of these, RBC, WBC, PLT, MCH, MCV, RDW, MPV, NEUT%, MONO%, LYMP%, EO%, and BASO% are quantitated by direct measurement, and HCT, HGB, MCHC, NEUT#, MONO#, LYMPH#, EO#, and BASO# are calculated from the direct measurements.

B Instrument Description Information:

1. Instrument Name:

   HemoScreen Hematology Analyzer

2. Specimen Identification:

Specimen identification is performed by manual keyboard entry or use of a barcode reader.

3. Specimen Sampling and Handling:

   HemoScreen can be used with either capillary or venous anticoagulated whole blood, collected in K2EDTA. Capillary blood sampling is performed by routine fingertip puncture using a standard lancet. The blood is collected in an K2EDTA microtube (indirect sampling) which is then taken into Sampler or directly from fingertip drawn into Sampler (direct sampling). Venous blood, thoroughly mixed and at room temperature, can be used as well.

4. Calibration:

   Factory calibration. The calibration of HemoScreen is traceable to the reference methods described in CLSI H26-A2.

5. Quality Control:

   The HemoScreen system includes both on-board internal and external quality controls. Internal quality control includes built-in self-tests, whereby the software verifies performance of the optics, reagent mixing, and instrument pneumatics. Every time the analyzer is turned on, and before each measurement, it automatically verifies conformance to the measurement specifications. Furthermore, internal self-testing occurs after the cartridge has been inserted, thus validating the integrity of the disposable unit. The intensity and spectrum of all illumination sources are tested using corresponding sensors, and the optical properties of each cartridge are inspected automatically prior to each test.

   Liquid Quality Controls (PIX-CBC): PIX-CBC Hematology Controls, 3-level commercial liquid quality controls are used to cover all HemoScreen parameters. CBC-PIX is a reagent composed of human erythrocytes and mammalian leukocytes and platelets suspended in a plasma-like fluid with preservatives. PIX-CBC whole blood controls (Cat No. PIX002) are produced by R&D Systems, a Bio-Techne brand, Minneapolis, MN.

V Substantial Equivalence Information:

A Predicate Device Name(s):
HemoScreen Hematology Analyzer

B Predicate 510(k) Number(s):
K222148

C Comparison with Predicate(s):

Device & Predicate Device(s):	K240636	K222148
Device Trade Name	HemoScreen Hematology Analyzer	Same
General Device Characteristic Similarities		

Intended Use/Indications For Use	The HemoScreen is a point-of-care (POC) automated hematology analyzer intended for the enumeration and classification of the following parameters in capillary and venous whole blood (K_2EDTA anticoagulated): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEUT%, NEUT#, LYMP%, LYMP#, MONO%, MONO#, EO%, EO#, BASO%, and BASO#. The HemoScreen is for in vitro diagnostic use in clinical laboratories and/or POC settings for adults and children at least 2 years of age.	Same
Parameters Measured	Red blood cells (RBC), White blood cells (WBC), Platelets (PLT), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular (erythrocyte) Volume (MCV), Mean Cell (erythrocyte) Hemoglobin (MCH), Mean cell (erythrocyte) Hemoglobin Concentration (MCHC), Red blood cell Distribution width (RDW)-CV Mean Platelets Volume (MPV), Neutrophils (NEUT; #/%), Monocytes (MONO; #/%), Lymphocytes (LYMP; #/%), Eosinophils (EO; #/%) and Basophiles (BASO; #/%)	Same
Throughput	10 samples/hour	Same
Test Principle	The HemoScreen uses a novel focusing method called viscoelastic focusing which causes the cells to perfectly align into a plane. High resolution microscopic images are taken of the flowing cells. Each image is analyzed using machine vision algorithms and the different cell types are differentiated and counted. WBCs are stained prior to analysis so as to enable differentiation between their subtypes and abnormal cells. Hb is calculated based on the optical density measured on intact individual	Same

	cells.	
Calibration	Factory calibrated	Same
Sample Type	Anticoagulated whole blood	Same
Sample Type- venous	K_2EDTA anticoagulated whole blood	Same
Sample Type-fingerstick	Direct and indirect *Direct*: Capillary blood from fingertip drawn directly into Sampler. *Indirect:* Capillary blood from fingertip delivered to microtainer, then transferred into Sampler	Same
Sample Volume	40 µL	Same
General Device Characteristic Differences		
Analytical Measuring Range (AMR) for WBC and PLT	WBC: 0.25–95 x 10^3/µL PLT: 7–988 x 10^3/µL	WBC: 0.5–80 x 10^3/µL PLT: 20–800 x 10^3/µL
Software Version	2.1.1	2.0.8

VI Standards/Guidance Documents Referenced:

CLSI EP06, 2nd Ed: Evaluation of Linearity of Quantitative Measurement Procedures; Approved guideline – Second edition, 2020

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved guideline, 2012

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Please refer to K222148 and K180020.

2. Linearity:

   The study was performed based on the recommendations of CLSI EP06, 2nd Edition. Linearity was defined for WBC and PLT by using serial dilutions prepared from the commercial linearity controls (PIX-LINE). Samples with ten levels were measured in seven replicates on a single HemoScreen analyzer. Results were examined for outliers and other potential problematic values. Linearity analysis was based on expected values at each sample

level. WBC and PLT parameters were confirmed to be linear across all tested points across the measuring ranges. The new ranges are presented in the table below.

Measurand	Linearity	Analytical Measuring Range
WBC (10^3/µL)	0.25 – 95.0	0.25 – 95.0
PLT (10^3/µL)	7.0 – 988.0	7.0 – 988.0

3. Analytical Specificity/Interference:

Please refer to K180020.

4. Accuracy (Instrument):

A method comparison study was conducted at one site to assess the performance of the HemoScreen compared to Sysmex XN-Series (XN-10, XN-20) Automated Hematology Analyzers (K112605) with the extended PLT and WBC ranges. A total of 232 residual whole blood venous samples that span the HemoScreen extended linear ranges and medical decision points were selected. The data were evaluated by Passing-Bablok regression and Pearson's correlation for all 20 parameters. For the regression analysis, the 95% confidence intervals (CI) and predicted bias/difference for each parameter were determined and the summarized data are provided below. All results were within the pre-defined acceptance criteria.

Passing-Bablok regression and Pearson's correlation of HemoScreen vs. Sysmex XN

Parameter	Result Range	Correlation Coefficient (r)	Intercept (95% CI)	Slope (95% CI)
WBC (10^3/µL)	0.29–94.77	0.995	-0.035 (-0.114, 0.027)	1.001 (0.992, 1.012)
RBC (10^6/µL)	1.91–7.13	0.997	0.023 (-0.015, 0.063)	0.998 (0.988, 1.009)
HGB (g/dL)	5.65–20.72	0.995	-0.006 (-0.153, 0.137)	0.993 (0.982, 1.005)
HCT (%)	16.42–62.73	0.990	-0.180 (-0.816, 0.385)	1.006 (0.991, 1.022)
MCV (fL)	53.33–111.47	0.928	1.818 (-2.268, 6.512)	0.979 (0.927, 1.025)
MCH (pg)	16.94–37.24	0.970	0.970 (0.428, 1.476)	0.953 (0.936, 0.973)
MCHC (g/dL)	30.90–36.06	0.654	10.582 (8.171, 13.072)	0.677 (0.603, 0.748)
RDW (%)	11.32–27.34	0.911	0.411 (-0.508, 1.273)	0.955 (0.889, 1.025)
PLT (10^3/µL)	9.25–930.66	0.991	0.317 (-3.176, 3.524)	0.985 (0.966, 1.004)
MPV (fL)	9.27–14.46	0.825	-0.432 (-1.329, 0.505)	1.055 (0.967, 1.138)
NEUT # (10^3/µL)	0.00–83.11	0.994	-0.042 (-0.130, 0.011)	1.017 (0.999, 1.033)

Parameter	Result Range	Correlation Coefficient (r)	Intercept (95% CI)	Slope (95% CI)
LYMP # (10^3/µL)	0.01–72.19	0.947	0.011 (-0.025, 0.053)	0.998 (0.968, 1.033)
MONO # (10^3/µL)	0.01–9.48	0.930	-0.006 (-0.031, 0.007)	1.006 (0.964, 1.056)
EO # (10^3/µL)	0.00–4.10	0.946	0.008 (0.004, 0.012)	0.998 (0.966, 1.031)
BASO # (10^3/µL)	0.00–0.77	0.415	-0.006 (-0.016, -0.001)	0.758 (0.593, 0.996)
NEUT (%)	0.90–98.20	0.961	0.158 (-1.138, 1.465)	1.012 (0.991, 1.033)
LYMP (%)	1.30–93.10	0.980	0.717 (0.395, 1.139)	0.986 (0.967, 1.005)
MONO (%)	0.10–45.80	0.877	-0.146 (-0.581, 0.255)	1.005 (0.947, 1.061)
EO (%)	0.00–34.10	0.855	0.087 (0.032, 0.100)	1.016 (1.000, 1.046)
BASO (%)	0.00–6.50	0.277	-0.076 (-0.193, -0.020)	0.764 (0.628, 0.967)

5. Carry-Over:

   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Limits of Detection, Blank, and Quantitation (LoD, LoB, and LoQ)

Five residual normal venous blood samples (from both morphological and cell distribution aspects) were centrifuged to deplete the plasma supernatant of RBCs, WBCs and PLTs. Each of the five plasma samples was assayed six times on two HemoScreen devices for a total of 60 measurements per parameter, using three cartridge and sampler lots. The limit of blank was determined by the 95th percentile of the distribution of the study variable.

To determine the LoD and LoQ for WBC and PLT, five low level samples were derived from native whole blood. Each of the five plasma samples was assayed six times on two HemoScreen devices for a total of 60 measurements per parameter, using three cartridge and sampler lots. The results for WBC and PLT were collected and used further for statistical analysis. The LoDs and LoQs were calculated in accordance with CLSI EP17-A2 using the parametric option.

Summary LoB, LoD and LoQ for WBC and PLT

Measurand	LoB	LoD	LoQ
WBC (x10^3/µL)	0.12	0.23	0.23
PLT (x10^3/µL)	0.52	2.73	2.73

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.