510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K222148

B Applicant

PixCell Medical Technologies, Ltd.

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 add an additional sample type (direct capillary fingerstick sampling to K2EDTA Sampler).

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

D Special Instrument Requirements:

HemoScreen Hematology Analyzer

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; #/%), eosinophiles (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 Principle of Operation:

The HemoScreen analyzer includes several modules (optical, mechanical, and electrical modules), a processor and controller that work together to measure blood samples that have been prepared inside disposable cartridges. The blood sample is collected with an additional disposable unit called a sampler. Once filled, the sampler is inserted into the cartridge in a single action, whereupon the cartridge is inserted into the reader for automatic sample preparation/staining and measurement. The cartridge is supplied preloaded with all required reagents.

Once the cartridge is inserted into the reader, blood is expelled from the capillaries into the reagent compartments. The reader then mixes the blood sample with the reagents by alternately pressing compressible portions of the cartridge, eventually causing the suspension of cells to flow into the microfluidic chamber. Cells flowing in the microfluidic chamber focus into a single-cell plane due to viscoelastic focusing. The reader then captures images of the focused cells and analyzes them in real time using machine vision algorithms. The reader interfaces with the cartridge mechanically and optically, and has no direct contact with the fluid inside the cartridge. When analysis is complete, the results are displayed to the user on the reader's touch screen.

Leukocytes are classified based on their staining properties and morphology, whereas absolute counts are obtained by counting the cells contained in a chamber of predetermined volume. Test results are obtained within six minutes and the results are saved.

C 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):
K180020

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222148	K180020
Device Trade Name	HemoScreen Hematology Analyzer	HemoScreen Hematology Analyzer
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 (K2EDTA anticoagulated): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEUT%,	Same

	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.	
Parameters tested	• 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; #/%) • Basophiles (BASO; #/%)	Same
Throughput	10 samples/hr	Same
Test Principle	The HemoScreen uses a novel focusing method called viscoelastic focusing which causes the cells to perfectly align into	Same

	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. HGB is calculated based on the optical density measured on intact individual cells.	
Calibration	Factory calibrated	Same
Sample Type – venous	K2EDTA anticoagulated whole blood	Same
Sample Volume	40 µL	Same
General Device Characteristic Differences		
Sample Type – fingerstick	Direct and Indirect Direct sampling where blood is directly collected from fingerstick into Sampler and Indirect method where capillary blood is collected from fingerstick into a K2EDTA microtube and then Sampler	Indirect Only: Capillary blood is collected from fingerstick into a K2EDTA microtube and then Sampler
Software version	2.0.8	1.10.12

VI Standards/Guidance Documents Referenced:

- CLSI H26-A2: Validation, verification, and quality assurance of automated hematology analyzers; Approved Standard-Second edition, 2010
- AAMI ANSI BP22:1994 (R2011) Blood Pressure Transducers

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision: Precision was conducted with three POC operators at one site for five days with three cartridge lots to assess within-run precision (repeatability) for direct capillary collection. Twenty-three (23) capillary blood samples were collected from subjects with 18 samples from healthy volunteers. For each reported parameter, the mean, SD and %CV with the 95% CI was calculated for repeatability. All results met the pre-defined acceptance criteria.

Parameter	Range	Mean	Repeatability (SD)	Repeatability (%CV)
WBC ($10^3/\mu L$)	<4.0	2.46	0.12	4.70
	>4.0	7.04	0.50	7.16
RBC ($10^6/\mu L$)	<3.5	2.30	0.07	2.91
	>3.5	4.63	0.11	2.43
HGB (g/dL)	<11.0	7.76	0.23	2.94
	>11.0	13.89	0.34	2.45
HCT (%)	10–70	35.89	0.87	2.44
MCV (fL)	50.0 to 150.0	87.93	0.29	0.33
MCH (pg)	10.0 to 45.0	30.76	0.08	0.26
MCHC (g/dL)	26.0 to 38.0	34.97	0.11	0.31
RDW (%)	10.0 to 40.0	14.09	0.03	0.23
PLT ($10^3/\mu L$)	<150	65.68	1.94	2.96
	>150	248.35	11.99	4.83
MPV (fL)	7.0 to 25.0	11.20	0.15	1.32
NEU# ($10^3/\mu L$)	WBC < 4.0 x $10^3/\mu L$	1.04	0.06	5.53
	WBC > 4.0 x $10^3/\mu L$	3.98	0.32	8.04
LYM# ($10^3/\mu L$)	WBC < 4.0 x $10^3/\mu L$	1.16	0.07	6.02
	WBC > 4.0 x $10^3/\mu L$	2.39	0.18	7.53
MON# ($10^3/\mu L$)	WBC < 4.0 x $10^3/\mu L$	0.22	0.05	20.19
	WBC > 4.0 x $10^3/\mu L$	0.48	0.07	14.81
EOS# ($10^3/\mu L$)	WBC < 4.0 x $10^3/\mu L$	0.02	0.00	27.22
	WBC > 4.0 x $10^3/\mu L$	0.12	0.02	15.10
BAS# ($10^3/\mu L$)	WBC < 4.0 x $10^3/\mu L$	0.02	0.01	59.60
	WBC > 4.0 x $10^3/\mu L$	0.06	0.02	42.67

Parameter	Range	Mean	Repeatability (SD)	Repeatability (%CV)
NEU%	WBC < 4.0 x $10^3/\mu L$	39.35	1.47	3.74
	WBC > 4.0 x $10^3/\mu L$	57.14	1.49	2.61
LYM%	WBC < 4.0 x $10^3/\mu L$	50.53	1.86	3.68
	WBC > 4.0 x $10^3/\mu L$	33.47	1.38	4.12
MON%	WBC < 4.0 x $10^3/\mu L$	8.85	2.88	32.55
	WBC > 4.0 x $10^3/\mu L$	6.86	0.78	11.37
EOS%	WBC < 4.0 x $10^3/\mu L$	0.53	0.25	47.19
	WBC > 4.0 x $10^3/\mu L$	1.72	0.34	19.45
BAS%	WBC < 4.0 x $10^3/\mu L$	0.73	0.37	50.41
	WBC > 4.0 x $10^3/\mu L$	0.81	0.38	47.15

2. Linearity:

   Please refer to K180020.

3. Analytical Specificity/Interference:

   Please refer to K180020.

4. Accuracy (Instrument):

   Please refer to K180020.

5. Carry-Over:

   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

1. Matrix Comparison Study:

   This study was conducted to demonstrate comparability between direct blood sampling where blood was collected directly into Sampler and indirect sampling where blood collected into a K2EDTA microtube. A matrix comparison study was performed at one (1) site with clinical laboratory and POC operators on forty-two (42) subjects. Blood was drawn twice from each donor and same finger if possible. The microtube capillary samples were assayed in duplicate on two HemoScreen devices. The first reportable direct result was used, and

these results were compared to the mean of duplicate of the indirect results. The data were evaluated by Passing-Bablok regression and Pearson's correlation for all 20 parameters. All results met the pre-defined acceptance criteria.

Parameter	N	Result Range	Intercept (95% CI)	Slope (95% CI)	Pearson Correlation
WBC ($10^3/\mu L$)	42	4.73–12.68	-0.216 (-0.893, 0.412)	1.028 (0.955, 1.108)	0.978
RBC ($10^6/\mu L$)	42	4.14–5.96	0 (-0.401, 0.498)	0.994 (0.881, 1.078)	0.97
HGB (g/dL)	42	12–17.7	-0.749 (-2.348, 1.097)	1.048 (0.913, 1.156)	0.969
HCT (%)	42	36.3–50.4	-1.77 (-7.048, 3.527)	1.032 (0.901, 1.157)	0.967
MCV (fL)	42	76.8–93.1	1.013 (-2.325, 3.887)	0.988 (0.954, 1.025)	0.994
MCH (pg)	42	24.6–33	-0.191 (-0.907, 0.605)	1.007 (0.981, 1.032)	0.998
MCHC (g/dL)	42	32–35.8	-1.519 (-4.767, 1.859)	1.047 (0.949, 1.143)	0.961
RDW (%)	42	11.6–14.3	-0.25 (-0.876, 0.266)	1.019 (0.977, 1.068)	0.991
PLT ($10^3/\mu L$)	42	137–394	3.646 (-16.602, 21.01)	0.963 (0.894, 1.051)	0.979
MPV (fL)	42	9.2–13.4	0.572 (-1.036, 1.837)	0.949 (0.832, 1.113)	0.92
NEUT ($10^3/\mu L$)	42	2.31–8.36	-0.221 (-0.531, 0.062)	1.049 (0.995, 1.109)	0.984
LYMP ($10^3/\mu L$)	42	1.6–4.59	-0.153 (-0.562, 0.251)	1.075 (0.925, 1.273)	0.953
MONO ($10^3/\mu L$)	42	0.22–0.75	-0.087 (-0.256, 0.023)	0.996 (0.796, 1.358)	0.825
EO ($10^3/\mu L$)	42	0.02–0.55	-0.021 (-0.032, -0.005)	1.017 (0.945, 1.081)	0.988
BASO ($10^3/\mu L$)	42	0.01–0.06	0.003 (-0.01, 0.012)	1.225 (0.842, 1.659)	0.598
NEUT (%)	42	47.1–72.2	-2.615 (-11.774, 4.007)	1.05 (0.941, 1.194)	0.957
LYMP (%)	42	19.5–44.9	-1.418 (-4.219, 1.404)	1.073 (0.983, 1.162)	0.969
MONO (%)	42	3–10.5	-2.108 (-3.977, -0.95)	1.147 (0.985, 1.459)	0.823
EO (%)	42	0.3–7.2	-0.27 (-0.429, -0.028)	1.029 (0.968, 1.097)	0.987
BASO (%)	42	0.1–0.9	-0.075 (-0.3, 0.15)	1.5 (1, 2)	0.614

2. Transportation Environmental Test:

To support the updated transport conditions for the HemoScreen Sampler and Cartridge modified from the original conditions cleared in K180020, additional testing was conducted to support the conditions using ASTM D4332 and D5276 standards. The

Temperature/Humidity Cycling study assessed different sequences for temperature (-10°C, 23°C, 55°C) and humidity (≥90%, ≤30%). The device package underwent temperature sequence at 23°C (90%Rh) for 24 hours and then -10°C for 24 hours. Within one (1) hour of the temperature testing, drop/disturbance testing was conducted from different angles of the package. The package underwent second cycle of temperature conditions at 23°C (90%Rh) for 24 hours and then 55°C (30%Rh) for 24 hours. A second drop test was conducted within an hour of the temperature testing. The performance passed the pre-defined acceptance criteria.

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.