510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K180020

B. Purpose for Submission:

Clearance of a new device

C. Manufacturer and Instrument Name:

PixCell Medical Technologies, Ltd.; HemoScreen Hematology Analyzer

D. Type of Test or Tests Performed:

Quantitative complete blood count with 5-part leukocyte differential: RBC, WBC, PLT, HGB, HCT, MCV, MCH, MCHC, RDW, MPV, NEUT#, NEUT%, MONO#, MONO%, LYMP#, LYMP%, EO#, EO% and BASO#, BASO%.

E. System Descriptions:

1. Device Description:

   The HemoScreen is a point-of-care (POC), automated hematology analyzer that provides results for 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), software, cartridge preloaded with reagents, 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 visoelastic focusing, lysis of red blood cells and white blood cell (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.

2. Principles 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.

3. 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 _____ or No ___X____

4. Specimen Identification:

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

5. 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, and the blood is collected in an K2EDTA microtube. Venous blood, thoroughly mixed and at room temperature, can be used as well.

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

7. Quality Control:

   The HemoScreen system includes both on-board internal and external quality controls.

   Internal quality control where the software verifies performance of the optics, reagent

mixing, and instrument pneumatics.

PIX-CBC Hematology Controls, 3-level commercial liquid quality controls will be used to cover all HemoScreen parameters. PIX-CBC Hematology controls are produced by R&D Systems, a Bio-Techne brand, Minneapolis, MN.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes___X____ or No_____

F. Regulatory Information:

1. Regulation section:

21 CFR 864.5220, Automated differential cell counter

2. Classification:

Class II

3 Product code:

GKZ – Counter, Differential Cell

4. Panel:

Hematology (81)

G. Intended Use:

1. 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.

2. Special Conditions for Use Statement(s):

For prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Sysmex® XN-Series (XN-10, XN-20) Automated Hematology Analyzer (Sysmex Analyzer) – K112605

2. Comparison with Predicate Device:

Similarities		
Item	Device HemoScreen	Predicate Sysmex XN Series
Intended 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.	The XN-Series modules (XN-10 and XN-20) modules are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K2 or K3EDTA anticoagulant and, Serous and Synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
Sample Type	Venous and capillary anticoagulated whole blood	Same

Differences		
Item	Device	Predicate
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, #/%) • Basophils (Baso; #/%)	• 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/SD • Mean Platelets Volume (MPV), • Neutrophils (NEUT; #/%), • Monocytes (MONO; #/%), • Lymphocytes (LYMP; #/%), • Eosinophils (EO; #/%) and • Basophils (BASO; #/%) • IG%/#, • NRBC#/%, • RET%/#, • IPF, IRF, • RET-He, • WBC-BF, (Body fluids) • RBC-BF, (Body fluids) • MN%/#, (Body fluids) • PMN%/#, (Body fluids) • TC-BF (Body fluids)
Throughput	10 samples/hour	100 samples/hour maximum depending on mode used
Test Principle	The HemoScreen uses 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 XN Series performs analyses using the following methods: fluorescence flow cytometry and sheath flow DC detection. The first is used to differentiate between WBC types and abnormal cells while the second is used for RBC and PLT analysis.

Differences		
Item	Device	Predicate
	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 individual intact cells.	The HGB is measured using a standard photometric method on the lysed RBC solution which is reacted with SLS forming a colored SLS-HGB complex.
Calibration	Factory calibrated	Requires calibration by the operator
Anticoagulant	K2EDTA	K2EDTA and K3DTA
Sample Volume	40 µL	88 µL

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP07-A2, Interference Testing In Clinical Chemistry; Approved Guideline -Second Edition

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition

J. Performance Characteristics*:*

1. Analytical Performance:
   a. Accuracy:

Method comparison studies were performed at three point-of-care (POC) sites (2 sites in the U.S. and one site in Israel) with 495 residual venous blood specimens collected in standard K2EDTA tubes. The studies included normal and pathological samples to assess the HemoScreen performance across the analytical measurement ranges (AMRs) as well as at medical decision points. The pathological samples included conditions: acute inflammation, bacterial and viral infections, aplastic anemia, acute and chronic leukemias (lymphocytic or myelocytic), multiple myeloma (plasma cell leukemia), microcytic anemia, normocytic anemia, macrocytic anemia, hemoglobinopathies, thalassemia, iron and folate deficiencies. The samples were represented by an age range of 4–92 years old, and the study population included 277 males (56%) and 218 females (44%). Each blood sample was analyzed in duplicate on the Hemoscreen and Sysmex XN-10, but only the first replicateHemoscreen results was used for all data analyses.

Bias was determined based on the results of the Deming regression model. For the regression analysis, the 95% confidence intervals (CI) and predicted bias/difference for each parameter was determined by sites and all sites combined. All results were within the pre-defined acceptance criteria with the exception of the basophil parameters.

Correlation of HemoScreen vs. Sysmex XN-10 -All sites combined

Parameter	Result Range	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
WBC ($10^3/\mu L$)	0.77 to 78.09	0.993	-0.256 (-0.396, -0.116)	1.040 (1.019, 1.061)
RBC ($10^6/\mu L$)	1.15 to 7.91	0.989	0.021 (-0.047, 0.088)	1.000 (0.983, 1.016)
HGB (g/dL)	3.94 to 24.20	0.985	-0.334 (-0.549, -0.119)	1.038 (1.019, 1.056)
HCT (%)	12.80 to 74.45	0.982	-0.184 (-0.872, 0.505)	1.036 (1.017, 1.056)
MCV (fL)	54.20 to 131.38	0.956	-2.367 (-6.216, 1.482)	1.053 (1.009, 1.096)
MCH (pg)	15.47 to 44.00	0.957	0.131 (-0.560, 0.822)	0.998 (0.974, 1.021)
MCHC (g/dL)	27.78 to 37.12	0.675	8.309 (5.921, 10.697)	0.727 (0.655, 0.799)
RDW (%)	11.94 to 31.29	0.946	0.504 (-0.018, 1.025)	0.965 (0.928, 1.002
PLT ($10^3/\mu L$)	20.17 to 771.57	0.967	-6.581 (-10.494, -2.668)	1.093 (1.068, 1.118)
MPV (fL)	8.73 to 20.28	0.831	0.043 (-0.660, 0.745)	1.016 (0.949, 1.082)
NEUT# ($10^3/\mu L$)	0.18 to 64.05	0.989	0.026 (-0.069, 0.120)	1.032 (1.007, 1.057)
LYMPH# ($10^3/\mu L$)	0.06 to 70.89	0.997	-0.003 (-0.037, 0.032)	1.058 (1.035, 1.082)
MONO# ($10^3/\mu L$)	0.01 to 24.55	0.718	-0.014 (-0.077, 0.049)	0.781 (0.671, 0.892)
EO#	0.00 to 2.97	0.981	-0.002	0.984

Parameter	Result Range	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
(10^3/µL)			(-0.007, 0.003)	(0.915, 1.053)
BASO# (10^3/µL)	0.00 to 0.21	0.055	-0.002 (-0.005, 0.001)	0.240 (0.166, 0.330)
NEUT%	6.91 to 97.45	0.984	2.161 (1.182, 3.139)	0.996 (0.978, 1.014)
LYMPH%	1.37 to 90.78	0.991	0.411 (-0.011, 0.833)	1.029 (1.007, 1.051)
MONO%	0.51 to 42.06	0.780	-0.370 (-1.271, 0.531)	0.809 (0.693, 0.924)
EO%	0.00 to 24.07	0.981	0.005 (-0.002, 0.013)	0.949 (0.893, 1.006)
BASO%	0.00 to 2.24	0.098	-0.009 (-0.044, 0.023)	0.214 (0.148, 0.293)

For the comparison of the HemoScreen to the Sysmex XN-10, the range of results was limited to 0.00–2.24; therefore, an additional method comparison study was conducted to evaluate the WBC differential parameters with elevated basophils. This study was conducted at one site with 95 whole blood samples (2–88 years of age, 39 females and 56 males) comparing the HemoScreen to manual light microscopy (400 cells per blood film) for basophil percentages. The WBC differential absolute counts were compared to the Sysmex XN-10. Deming linear regression analysis was used to calculate the correlation coefficient, slope and intercept along with the 95% CI. The results met the pre-defined acceptance criteria.

WBC differential analysis with elevated basophil samples

Parameter	Result Range	Comparator	Correlation Coefficient	Intercept (95% CI)	Slope (95% CI)
NEUT# (10^3/µL)	0.49 to 27.74	Sysmex	0.988	-0.005 (-0.122, 0.111)	0.962 (0.921, 1.002)
LYMPH# (10^3/µL)	0.12 to 23.75	Sysmex	0.982	0.022 (-0.119, 0.162)	1.159 (1.025, 1.294)
MONO# (10^3/µL)	0.08 to 7.04	Sysmex	0.930	0.014 (-0.035, 0.062)	0.955 (0.846, 1.064)
EO# (10^3/µL)	0.00 to 1.71	Sysmex	0.940	0.006 (0.001, 0.011)	1.082 (0.918, 1.247)
BASO# (10^3/µL)	0.00 to 1.69	Sysmex	0.484	0.007 (-0.008, 0.023)	0.866 (0.333, 1.398)
NEU%	13.89 to 92.56	Blood Smear	0.916	7.477 (-16.142, 31.096)	0.768 (0.381, 1.155)
LYMPH%	1.52 to 82.49	Blood Smear	0.921	1.456 (-0.595, 3.507)	1.214 (1.041, 1.388)
MONO%	1.25 to 45.43	Blood Smear	0.762	1.190 (0.221, 2.159)	1.230 (1.036, 1.423)
EO%	0.00 to 19.50	Blood Smear	0.915	0.022 (-0.031, 0.075)	1.342 (1.016, 1.668)
BASO%	0.13 to 12.22	Blood Smear	0.725	0.334 (0.260, 0.408)	0.466 (0.209, 0.724)

Flagging studies

The WBC flagging rate for HemoScreen was compared to the WBC differential results displayed by the Sysmex XN and CellaVision for 460 samples. Three blood film slides were prepared for each sample for measurement on the CellaVision (2 slides/200 cells counted per slide for a total of 400 cells). Competent operators trained to use the CellaVision performed the differentials, and the results were verified by these operators. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the parameters resides outside of the normal concentrations, and (2) morphological abnormal samples, which are samples that contain atypical forms of the normal cell types contained in ordinary blood samples.

Overall WBC Flagging, HemoScreen versus Predicate

All Sites	95% CI
Positive Percent Agreement	95.9 (93.0, 97.9)
Negative Percent Agreement	82.1 (73.4, 88.8)
% Overall Agreement	92.3 (89.2, 94.7)

Overall WBC Flagging, HemoScreen versus Blood Smear

All Sites	95% CI
Positive Percent Agreement	93.8 (90.3, 96.3)
Negative Percent Agreement	71.7 (62.4, 79.8)
% Overall Agreement	87.6 (83.9, 90.6)

b. Precision/Reproducibility:

Repeatability-Whole blood

Two short term precision studies were conducted across three sites (one internal site and 2 POC sites) with POC operators to assess within-run precision (repeatability) in accordance with the CLSI EP05-A3 approved guideline. Sixty-five K2EDTA whole blood samples that spanned the analytical measuring range and medical decision levels were assayed 15 times and for all 20 parameters. All results met the pre-defined acceptance criteria.

Reproducibility-Whole blood

The study was conducted at three sites, over five days with five replicates per run using a 3-level control set comprising low, normal and high levels of measurands. The data generated from this assessment was used to calculate, between-day and between-run precision, between-laboratory precision (includes variability of different systems and operators), and reproducibility (total precision). For each reported parameter and for each level of control tested, the mean, SD and %CV of the various

components of precision were calculated along with the 95% CI of the SD and %CV for repeatability and reproducibility (total precision). The results were analyzed in accordance with the CLSI EP05-A3 approved guideline and met the pre-acceptance defined criteria.

All Sites Combined			Between-run		Between-Day		Between-site		Total	
Measurand	Level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	Low	2.82	0.203	7.2%	0.000	0.0%	0.116	4.1%	0.234	8.3%
WBC	Normal	8.98	0.424	4.7%	0.078	0.9%	0.234	2.6%	0.490	5.5%
WBC	High	20.62	0.802	3.9%	0.219	1.1%	0.355	1.7%	0.904	4.4%
RBC	Low	2.66	0.052	1.9%	0.011	0.4%	0.040	1.5%	0.066	2.5%
RBC	Normal	4.93	0.096	1.9%	0.016	0.3%	0.065	1.3%	0.117	2.4%
RBC	High	5.92	0.108	1.8%	0.020	0.3%	0.038	0.6%	0.116	2.0%
HGB	Low	7.01	0.168	2.4%	0.049	0.7%	0.045	0.6%	0.181	2.6%
HGB	Normal	15.48	0.430	2.8%	0.078	0.5%	0.075	0.5%	0.444	2.9%
HGB	High	22.04	0.469	2.1%	0.076	0.3%	0.073	0.3%	0.481	2.2%
HCT	Low	19.01	0.376	2.0%	0.073	0.4%	0.340	1.8%	0.512	2.7%
HCT	Normal	40.48	0.819	2.0%	0.080	0.2%	0.567	1.4%	0.999	2.5%
HCT	High	57.32	1.077	1.9%	0.214	0.4%	0.334	0.6%	1.148	2.0%
MCV	Low	71.42	0.438	0.6%	0.000	0.0%	0.506	0.7%	0.669	0.9%
MCV	Normal	82.19	0.526	0.6%	0.000	0.0%	0.273	0.3%	0.593	0.7%
MCV	High	96.90	0.486	0.5%	0.116	0.1%	0.280	0.3%	0.573	0.6%
MCH	Low	26.32	0.465	1.8%	0.000	0.0%	0.218	0.8%	0.513	1.9%
MCH	Normal	31.43	0.442	1.4%	0.084	0.3%	0.198	0.6%	0.492	1.6%
MCH	High	37.26	0.402	1.1%	0.070	0.2%	0.319	0.9%	0.518	1.4%
MCHC	Low	36.86	0.764	2.1%	0.023	0.1%	0.502	1.4%	0.915	2.5%
MCHC	Normal	38.24	0.648	1.7%	0.111	0.3%	0.312	0.8%	0.727	1.9%
MCHC	High	38.46	0.491	1.3%	0.125	0.3%	0.379	1.0%	0.633	1.6%
RDW	Low	13.80	0.114	0.8%	0.000	0.0%	0.112	0.8%	0.160	1.2%
RDW	Normal	16.57	0.072	0.4%	0.000	0.0%	0.129	0.8%	0.148	0.9%
RDW	High	13.79	0.193	1.4%	0.097	0.7%	0.180	1.3%	0.281	2.0%
PLT	Low	70.71	3.408	4.8%	1.329	1.9%	4.222	6.0%	5.586	7.9%
PLT	Normal	269.42	9.208	3.4%	3.300	1.2%	11.328	4.2%	14.967	5.6%
PLT	High	567.99	17.348	3.1%	2.958	0.5%	14.760	2.6%	22.969	4.0%
MPV	Low	9.91	0.084	0.8%	0.000	0.0%	0.057	0.6%	0.101	1.0%
MPV	Normal	9.82	0.069	0.7%	0.014	0.1%	0.051	0.5%	0.087	0.9%
MPV	High	9.98	0.062	0.6%	0.004	0.0%	0.051	0.5%	0.080	0.8%
NEU#	Low	1.48	0.120	8.1%	0.010	0.7%	0.043	2.9%	0.128	8.6%
NEU#	Normal	4.44	0.221	5.0%	0.000	0.0%	0.000	0.0%	0.221	5.0%
NEU#	High	9.17	0.544	5.9%	0.107	1.2%	0.532	5.8%	0.768	8.4%
LYM#	Low	0.97	0.094	9.6%	0.000	0.0%	0.070	7.2%	0.117	12.0%
LYM#	Normal	3.34	0.211	6.3%	0.098	2.9%	0.232	7.0%	0.329	9.8%
LYM#	High	9.02	0.640	7.1%	0.150	1.7%	0.737	8.2%	0.987	10.9%
MON#	Low	0.25	0.040	15.6%	0.012	4.7%	0.000	0.0%	0.042	16.3%
MON#	Normal	0.86	0.078	9.1%	0.000	0.0%	0.013	1.5%	0.079	9.2%
MON#	High	1.66	0.126	7.6%	0.000	0.0%	0.025	1.5%	0.129	7.8%
EOS#	Low	0.10	0.020	21.2%	0.000	0.0%	0.000	0.0%	0.020	21.2%
EOS#	Normal	0.30	0.041	13.7%	0.000	0.0%	0.007	2.4%	0.042	13.9%
EOS#	High	0.69	0.059	8.5%	0.000	0.0%	0.012	1.8%	0.060	8.7%
BAS#	Low	0.01	0.002	15.3%	0.000	2.5%	0.001	4.5%	0.002	16.1%
BAS#	Normal	0.04	0.004	10.0%	0.000	0.0%	0.002	4.0%	0.004	10.8%

All Sites Combined			Between-run		Between-Day		Between-site		Total	
Measurand	Level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
BAS#	High	0.09	0.005	6.3%	0.001	1.4%	0.002	2.5%	0.006	6.9%
NEU%	Low	52.57	2.002	3.8%	0.000	0.0%	0.419	0.8%	2.046	3.9%
NEU%	Normal	49.49	1.340	2.7%	0.443	0.9%	1.388	2.8%	1.979	4.0%
NEU%	High	44.48	2.313	5.2%	0.240	0.5%	2.893	6.5%	3.712	8.3%
LYM%	Low	34.55	2.022	5.9%	0.357	1.0%	1.000	2.9%	2.284	6.6%
LYM%	Normal	37.16	1.237	3.3%	0.641	1.7%	1.584	4.3%	2.109	5.7%
LYM%	High	43.73	2.421	5.5%	0.383	0.9%	3.017	6.9%	3.888	8.9%
MON%	Low	9.04	1.276	14.1%	0.383	4.2%	0.259	2.9%	1.357	15.0%
MON%	Normal	9.56	0.777	8.1%	0.120	1.3%	0.273	2.9%	0.832	8.7%
MON%	High	8.05	0.458	5.7%	0.000	0.0%	0.102	1.3%	0.469	5.8%
EOS%	Low	3.42	0.698	20.4%	0.000	0.0%	0.025	0.7%	0.699	20.4%
EOS%	Normal	3.37	0.438	13.0%	0.000	0.0%	0.000	0.0%	0.438	13.0%
EOS%	High	3.33	0.249	7.5%	0.000	0.0%	0.120	3.6%	0.276	8.3%
BAS%	Low	0.42	0.052	12.4%	0.011	2.6%	0.000	0.0%	0.053	12.7%
BAS%	Normal	0.42	0.038	9.2%	0.000	0.0%	0.005	1.2%	0.039	9.2%
BAS%	High	0.41	0.021	5.0%	0.000	0.0%	0.001	0.3%	0.021	5.0%

c. *Linearity*:

Linearity was defined for WBC, RBC, HGB, HCT and PLT using 6 venous whole blood samples. These samples were contrived to create the test panels for WBC, RBC, HGB, HCT, and PLT to cover the specified ranges. Seven concentrations were used for RBC/HGB and HCT, 10 concentrations were used for PLT, and 14 concentrations were used for WBC. Each concentration level was tested in duplicate on each of the two HemoScreen analyzers.

Regression analysis was used to assess linearity for first order model (e.g. linear), and weighted polynomial regression was used to assess linearity for second and third order models (e.g, quadratic and cubic). PLT achieved linearity with a first order model while for all other parameters linearity was achieved through polynomial regression.

Measurand	**Analytical Measuring Range**
WBC (10^3/µL)	0.5-80.0
RBC (10^6/µL)	1.0-8.8
HGB (g/dL)	3.0-25.0
HCT (%)	9.0-78.0
PLT (10^3/µL)	20 -800

d. Carryover:

Not applicable

e. Interfering Substances:

The objective of the study was to evaluate the effect of various potential interfering substances and blood constituents on HemoScreen clinical and analytical performance. The scope of the potential interferents included lipemia, high bilirubin, high WBC, high PLT, and NRBCs.

There was no significant bilirubin interference up to a concentration 50 mg/dL for the following parameters: WBC, HGB, RBC, HCT, MCV, MCH, MCHC, and RDW. For PLT and MPV, there was no significant bilirubin interference up to a concentration of 30 mg/dL.

When blood samples with high triglycerides (319-729 mg/dL) were tested, it was confirmed that all parameters met the claims. There was no significant interference detected when evaluated at this concentration.

For high white blood cell (up to 317 $x10^3/\mu L$) and platelet (up to 2,045 $x10^3/\mu L$) concentrations, no significant bias was observed in any of the evaluated parameters and no significant NRBC interference was noted.

2. Other Supportive Instrument Performance Data Not Covered Above:

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

Limit of blank was determined using five plasma depleted residual normal venous blood samples. Each of the five plasma samples were assayed six times on two HemoScreen devices for a total of 60 measurements per parameter, using three cartridge and sampler lots. The study results are provided in the following table.

Parameter	LoB
WBC	0.0 x $10^3/\mu L$
RBC	0.0 x $10^6/\mu L$
HGB	0.0 g/dL
HCT	0.0%
PLT	0.0 x $10^3/\mu L$

To determine the LoD and LoQ for WBC, RBC, HGB, HCT and PLT, five low level samples were derived from native whole blood. Each of the prepared samples was assayed six times on each of the two HemoScreen devices for a total of 60 measurements. The results of the LoD and LoQ are provided in the table below.

Parameter	Units	LoD	LoQ
WBC	x 10^3/µL	0.2	0.51
RBC	x 10^6/µL	0.03	0.65
HGB	g/dL	0.11	1.87
HCT	%	0.28	5.66
PLT	x 10^3/µL	4.57	4.57

b. Capillary and venous whole blood comparison studies

This study was conducted to demonstrate comparability between capillary and venous blood from the same subject tested on the HemoScreen. This study was performed using 75 paired normal and abnormal whole blood samples that included clinical decision points for WBC, HGB, and PLT from three clinical sites. Blood was drawn twice from each donor, once via venipuncture (venous) and once via fingerstick (capillary). For all samples, results from the HemoScreen were comparable for capillary and venous blood. The venous whole blood sample results were compared to the corresponding results of the capillary samples for the same donor. All results met the pre-defined acceptance criteria.

c. Reference Intervals

Adult reference range

The normal adult reference interval for all parameters reported by the HemoScreen analyzer was established by analyzing venous whole blood samples collected in K2EDTA from a total population of 243 healthy individuals (N=120 males, N=123 females) collected at one site. Results were established by calculating the non-parametric 95% confidence interval (2.5^{th} to 97.5^{th} percentiles). The calculated normal reference ranges are listed below.

Parameter	Female (n=123)		Male (n=120)	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit
WBC (10^3/µL)	4.0	11.5	3.6	10.2
RBC (10^6/µL)	3.6	5.1	4.2	6.0
HGB (g/dL)	10.8	15.6	12.5	17.6
HCT (%)	32.9	45.6	39.0	52.0
MCV (fL)	78.1	99.2	74.9	98.0
MCH (pg)	24.4	32.8	23.8	32.8
MCHC (g/dL)	30.7	34.7	30.9	35.6
RDW (%)	11.7	16.1	11.8	14.9
PLT (10^3/µL)	179	450	141	437
MPV (fL)	9.6	14.0	9.3	15.9
NEUT# (10^3/µL)	1.8	8.4	1.7	7.4
LYMPH# (10^3/µL)	1.3	3.9	1.2	3.8
MONO# (10^3/µL)	0.1	0.6	0.1	0.8

Parameter	Female (n=123)		Male (n=120)	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit
EO# (10^3/µL)	0.0	0.4	0.0	0.5
BASO# (10^3/µL)	0.00	0.03	0.00	0.02
NEUT%	41.0	79.6	34.7	73.4
LYMPH%	16.7	51.7	20.7	56.9
MONO%	1.7	7.5	1.7	9.4
EO%	0.3	5.9	0.3	7.7
BASO%	0.0	0.3	0.0	0.4

Pediatric reference range

A peer review literature reference range was provided for the pediatric population, Soldin S, Brugnara C, Wong E (eds.) (2007): Pediatric reference intervals. 6th ed. *AACC Press*, Washington, DC, 217-71.

d. Sample Stability

Sample stability was determined for 18 freshly collected venous normal and abnormal blood samples. The venous blood samples were collected into K2EDTA tubes. The samples were subsequently kept at room temperature (20–25°C) and were analyzed again, in duplicate at the following time points: 2 hours, 4 hours, 6 hours, 7 hours and 8 hours. For each time point, results were compared to the respective baseline results. The data at each time point met the acceptance criteria. The data support a sample stability claim of 7 hours at room temperature.

e. Shipping and shelf life stability

The objective of this combined study was to evaluate the reagent cartridges and samplers (the system's disposable components). The packaging/shipping integrity, and shelf life claims of HemoScreen reagent cartridges along with the potential environmental effects that could be encountered during shipment under routine storage conditions (room temperature) were assessed.

Three cartridge lots were used for the environmental testing and for the shelf life testing (3.5 months, 6.5 months and 7 months): There was no significant effect on HemoScreen performance when comparing 3.5 month, 6.5 month and 7 month aged cartridges to newly produced cartridges. The results from all evaluations performed during this study met the predefined acceptance criteria. The data support a stability claim for 6.5 month for the system's disposable components.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.