510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K143577

B. Purpose for Submission:

Clearance of a new device

C. Manufacturer and Instrument Name:

Sysmex America Inc., Sysmex XW-100 and XW QC CHECK

D. Type of Test or Tests Performed:

Complete blood count (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV), leukocyte 3-part differential (LYM%, other WBC%, NEUT%, LYM#, other WBC#, NEUT#), RDW-SD and RDW-CV.

E. System Descriptions:

1. Device Description:
   The XW-100 Automated Hematology Analyzer, hereafter referred to as Sysmex XW-100, is an electrical resistance blood cell counter. The Sysmex XW-100 analyzes human whole blood specimens anticoagulated with dipotassium and tripotassium ethylenediaminetetraacetic acid (K_2EDTA and K_3EDTA) and reports results for the following 17 parameters: white blood cell (WBC), red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet (PLT), percent lymphocytes (LYM%), percent other WBC (WBC%), percent neutrophils (NEUT%), absolute lymphocytes (LYM#), absolute other WBC (WBC#), absolute neutrophils (NEUT#), red cell distribution width standard deviation (RDW-SD), red cell distribution width coefficient of variation (RDW-CV), and mean platelet volume (MPV).

2. Principles of Operation:
   The patient sample is aspirated, measured, diluted with diluent (and lysed for WBC and hemoglobin measurement), then directed into a transducer chamber by a hydrodynamic focusing nozzle. The transducer chamber has a minute hole, or aperture. Electrodes are mounted on both sides of the aperture chamber, through which the direct current flows. Blood cells suspended in the diluted sample are injected through the aperture by the hydrodynamic focusing nozzle. The hydrodynamic focusing nozzle is positioned in front of the aperture and in line with the aperture's center. This method improves cell counting accuracy because all blood cells are separated from each other and pass through the

aperture in one direction, one cell at a time. When a cell passes through the aperture, it causes a change in the direct current resistance, which is proportional to the cell's size. The resistance changes are captured as electric pulses. The various blood cell counts are calculated by counting the electric pulses that occur in each cell size category. The analyzer then determines blood cell volume and identifies rare and pathological cells by creating and analyzing histograms of the various cell populations using their respective pulse heights. Hemoglobin is measured photometrically by a non-cyanide method.

3. Modes of Operation:
   The Sysmex XW-100 operates by automated whole blood analysis.

   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 input is manual (by operator).

5. Specimen Sampling and Handling:
   Samples are manually mixed and loaded into an onboard sample adapter one at a time. The Sysmex XW-100 processes anticoagulated venous whole blood collected in K_2EDTA or K_3EDTA collection containers.

6. Calibration:
   The Sysmex XW-100 is factory calibrated.

7. Quality Control:
   Quality control performance is to be evaluated using XW QC CHECK, a 3-level stabilized whole blood matrix quality control material designed for the statistical process control of the Sysmex XW-100. Assayed parameters include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC %, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV.

8. Software:
   The software is purposed to operate the system featuring a simple and intuitive user interface and guide user workflows including instrument and error handling procedures.

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
   21 CFR § 864.8625, Hematology Quality Control Mixture

2. Classification:
   Class II

3 Product code:
   GKZ – Counter, Differential Cell
   JPK – Mixture, Hematology Quality Control

4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   Sysmex XW-100 Automated Hematology Analyzer
   The Sysmex XW-100™ is a quantitative automated hematology analyzer intended for *in vitro* diagnostic point-of-care use to classify and enumerate the following parameters for venous whole blood anticoagulated with K_2/K_3 EDTA: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV. It is not for use in diagnosing or monitoring oncology patients, children under the age of 2, or for chronically or critically ill patients.

   XW QC CHECK
   XW QC CHECK is a stabilized whole blood matrix designed for statistical process control of the Sysmex XW-100 automated hematology analyzer. It is not intended for calibration of the analyzer. Assayed parameters include WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV.

2. Special Conditions for Use Statement(s):
   The Sysmex XW-100™ is for use in ambulatory general practitioner's offices and is not intended for use in an environment where patients are critically or chronically ill such as emergency rooms, acute care centers, nursing or rehabilitation facilities.

   The Sysmex XW-100™ is intended to be used by operators with a minimum of an earned

high school diploma or equivalent and documented training in the use of the Sysmex XW-100™.

For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Names and 510(k) numbers:
   Sysmex® pocH-100i Automated Hematology Analyzer (K032677)
   Para Check Quality Control (K852992)

2. Comparison with Predicate Device:

Similarities		
Item	**Device**	**Predicate**
Intended Use	The Sysmex XW-100™ is a quantitative automated hematology analyzer intended for *in vitro* diagnostic point-of-care use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#, RDW-SD, RDW-CV, and MPV. It is not for use in diagnosing or monitoring oncology patients, children under the age of 2, or for chronically or critically ill patients.	The Sysmex pocH-100i Automated Hematology Analyzer is an automated cell counter intended for *in vitro* diagnostic use in CLIA non-waived clinical laboratories (not for Point of Care use in a CLIA waived laboratory).
Test Principle	Impedance technology (direct current detection) with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically.	Same
Measuring Channel	Single hydrodynamic focused impedance chamber	Same
Sample Type	Anticoagulated (K_2EDTA or K_3EDTA) venous whole blood	Same
Sample aspiration volume	15 µL	Same
Analysis Reagents	XW Pack L (lyse) XW Pack D (diluent)	Same
System Throughput	20 cycles per hour	Same
Test System Dimensions	Width: 7 inches Height: 14 inches Depth: 18 inches	Same

Differences		
Item	**Device**	**Predicate**
Sample Type	Anticoagulated (K_2EDTA or K_3EDTA) venous whole blood	Anticoagulated (K_2EDTA, K_3EDTA, or Na_2EDTA) venous whole blood
Mode of Operation	Whole blood mode	Whole blood mode Pre-dilute mode
Calibration and Quality Control	XW QC CHECK controls are stored in the laboratory at room (ambient) temperature at 15°C−25°C or 59°F−77°F. Range limits are downloaded automatically by an internet connection. Expiration, cycle use, and performance validity checks are monitored and enforced by the system via a QC lock-out mechanism. The Sysmex XW-100 is factory calibrated using the SCS™-1000 calibrator (K943268); calibration is not performed by the end-user (point-of-care operator).	EIGHTCHECK controls are stored in the laboratory at 2−8°C. Range limits are entered manually by the operator via keystroke input. Expiry, cycle use limitations, and valid performance are not monitored by the system. Calibration is performed on site by qualified personnel using the SCS™-1000 calibrator (K943268).

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

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

CLSI EP10-A3, Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline – Third Edition

CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition

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

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

CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition

CLSI EP09-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition

CLSI C24, Statistical QC for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline – Third Edition

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition

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

CLSI H18-A3, Procedure for the Handling and Processing of Blood Specimens; Approved Guideline – Third Edition

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Method Comparison

   Method comparison studies were performed across three point-of-care clinical sites (with three operators per site) to assess the performance of the Sysmex XW-100 compared to the Sysmex pocH-100*i* analyzer utilizing a total of 391 K_2EDTA venous whole blood samples. The study population included normal and abnormal pediatric (N=69) and adult subjects (N=322).

   Statistical analyses for the method comparison, demonstrating correlation between the Sysmex XW-100 and Sysmex pocH-100*i* analyzers, were provided based on Deming regressions and Bland-Altman plots for each blood parameter. The predefined acceptance criteria were successfully met.

Correlation and Estimated Bias of Sysmex XW-100 Compared to Sysmex pocH-100*i* - Combined Sites

Parameter	**N**	**(r)**	**Slope**	**95% CI**		**Intercept (95% CI)**	**95% CI**		**Mean Bias**	**Mean % Bias**
				Lower Limit	Upper Limit		Lower Limit	Upper Limit		
WBC	389	0.999	1.015	1.007	1.024	-0.028	-0.098	0.042	0.11	1.5
RBC	391	0.995	0.982	0.970	0.993	0.064	0.014	0.115	-0.01	-0.3
HGB	391	0.994	0.986	0.974	0.998	0.237	0.094	0.381	0.06	0.6
HCT	391	0.991	0.977	0.960	0.994	0.757	0.142	1.371	-0.10	-0.2
MCV	390	0.983	1.005	0.986	1.025	-0.490	-2.190	1.209	0.00	0.0
MCH	391	0.946	1.011	0.978	1.043	-0.074	-1.026	0.877	0.24	0.8
MCHC	391	0.761	1.114	0.998	1.231	-3.532	-7.408	0.343	0.25	0.8
PLT	391	0.994	0.994	0.981	1.008	1.145	-2.115	4.405	-0.22	0.2
MPV	377	0.961	0.990	0.958	1.021	0.232	-0.131	0.594	0.11	1.0
LYMPH%	316	0.993	1.003	0.988	1.018	0.084	-0.254	0.421	0.16	1.5
Other WBC%	315	0.765	1.107	1.009	1.206	-0.891	-1.734	-0.048	0.10	10.4
NEUT%	316	0.968	1.002	0.972	1.032	-0.381	-2.508	1.745	-0.24	-0.3
LYMPH#	316	0.994	1.021	1.008	1.034	-0.006	-0.031	0.019	0.03	2.2
Other WBC#	316	0.785	1.055	0.945	1.165	-0.031	-0.107	0.045	0.01	11.7

NEUT#	315	0.993	1.009	1.000	1.018	0.005	-0.049	0.060	0.06	1.1
RDW-SD	391	0.954	1.052	0.978	1.126	-1.904	-5.165	1.357	0.49	1.1
RDW-CV	390	0.989	1.012	0.990	1.034	-0.001	-0.312	0.311	0.18	1.2

b. *Flagging Comparison*

A flagging comparison study was performed across three point-of-care clinical sites to evaluate flagging agreement between the candidate and comparative methods, the Sysmex XW-100 and Sysmex pocH-100*i* respectively. The Sysmex XW-100 flagging system includes flagging limits (+/-) and particle distribution analysis (PDA) for all claimed parameters as described in the instructions for use (IFU). A two-sided 95% confidence interval (CI) for each agreement estimate was calculated using the Bayesian method provided below.

N=391	**Sysmex pocH-100*i***		
Sysmex XW-100	Positive	Negative	Total
Positive	257 (a)	10 (b)	267
Negative	7 (c)	117 (d)	124
Total	264	127	391

Positive Percent Agreement = 100 × a/(a+c) = 100 × 257/(257+7) = 97.3%
95% CI: 94.6% to 98.6%

Negative Percent Agreement = 100 × d/(d+b) = 100 × 117/(117+10) = 92.1%
95% CI: 86.1% to 95.6%

Overall Agreement = 100 × (a+d)/n =100 × (257+117)/(391)= 95.6%
95% CI: 93.1% to 97.2%

c. *Precision/Reproducibility*

Precision performance of the Sysmex XW-100 was evaluated by performing repeatability and reproducibility studies across three point-of-care (POC) clinical sites with the intended POC operators.

The repeatability study was conducted for the WBC, RBC, HGB, HCT and PLT parameters with residual whole blood samples collected in K_2EDTA collection containers. The samples were selected to span the medical decision levels, the lower and upper limits of the analytical measuring range. Each sample was analyzed 10 consecutive times. SD (standard deviation) and CV% (coefficient of variation) were calculated and provided for each measurand at each site. The predefined acceptance criteria were met.

Reproducibility performance was conducted at each site over 20 operating days utilizing three levels of commercial control material (XW QC CHECK – low, normal

and high) performing two runs per day and two replicates per run. To further demonstrate precision performance, SD (standard deviation) and CV% (coefficient of variation) of within-run, between-run, between-day, and between-device were calculated per site and for the combined sites for each measurand as shown below.

XW QC CHECK Low Level Control

Measurand	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	256	2.904	0.086	2.96	0.041	1.41	0.000	0.00	0.042	1.46	0.104	3.59
RBC	256	2.392	0.028	1.18	0.005	0.22	0.004	0.16	0.033	1.38	0.044	1.84
HGB	256	6.332	0.091	1.44	0.032	0.51	0.000	0.00	0.029	0.45	0.101	1.59
HCT	256	18.67	0.224	1.20	0.089	0.48	0.135	0.72	0.202	1.08	0.342	1.83
MCV	256	78.05	0.226	0.29	0.158	0.20	0.553	0.71	0.183	0.23	0.644	0.83
MCH	256	26.47	0.500	1.89	0.000	0.00	0.000	0.00	0.280	1.06	0.573	2.17
MCHC	256	33.92	0.659	1.94	0.000	0.00	0.321	0.95	0.237	0.70	0.770	2.27
PLT	256	56.80	2.759	4.86	0.000	0.00	1.454	2.56	1.079	1.90	3.299	5.81
MPV	256	10.53	0.275	2.61	0.000	0.00	0.067	0.64	0.023	0.22	0.284	2.69
LYMPH#	256	0.712	0.040	5.62	0.023	3.16	0.000	0.00	0.008	1.09	0.047	6.54
Other WBC#	254	0.259	0.061	23.52	0.000	0.00	0.007	2.85	0.008	3.11	0.062	23.89
NEUT#	254	1.933	0.094	4.87	0.018	0.92	0.010	0.50	0.024	1.22	0.099	5.13
LYMPH%	256	24.58	1.012	4.12	0.382	1.56	0.000	0.00	0.032	0.13	1.082	4.40
Other WBC%	254	8.875	1.880	21.18	0.000	0.00	0.000	0.00	0.000	0.00	1.880	21.18
NEUT%	254	66.56	2.140	3.22	0.000	0.00	0.358	0.54	0.000	0.00	2.170	3.26
RDW-SD	256	42.01	0.328	0.78	0.000	0.00	0.244	0.58	0.271	0.64	0.490	1.17
RDW-CV	256	15.26	0.106	0.69	0.067	0.44	0.143	0.94	0.081	0.53	0.207	1.36

XW QC CHECK Normal Level Control

Measurand	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	256	6.946	0.193	2.77	0.000	0.00	0.072	1.03	0.085	1.22	0.222	3.20
RBC	256	4.482	0.037	0.83	0.020	0.45	0.030	0.68	0.058	1.30	0.078	1.74
HGB	256	13.26	0.191	1.44	0.000	0.00	0.093	0.70	0.128	0.97	0.248	1.87
HCT	256	38.27	0.325	0.85	0.203	0.53	0.341	0.89	0.375	0.98	0.635	1.66
MCV	256	85.39	0.209	0.24	0.179	0.21	0.473	0.55	0.240	0.28	0.597	0.70
MCH	256	29.60	0.448	1.51	0.000	0.00	0.184	0.62	0.367	1.24	0.608	2.05
MCHC	256	34.67	0.539	1.56	0.000	0.00	0.364	1.05	0.361	1.04	0.744	2.15
PLT	256	222.5	5.890	2.65	1.259	0.57	3.118	1.40	4.920	2.21	8.379	3.77
MPV	256	10.20	0.146	1.44	0.027	0.26	0.086	0.84	0.034	0.34	0.175	1.72
LYMPH#	256	2.168	0.097	4.46	0.000	0.00	0.040	1.85	0.007	0.32	0.105	4.84
Other WBC#	254	0.689	0.104	15.08	0.033	4.75	0.000	0.00	0.023	3.38	0.111	16.16
NEUT#	254	4.089	0.170	4.15	0.000	0.00	0.047	1.14	0.050	1.22	0.183	4.47
LYMPH%	256	31.18	0.834	2.67	0.000	0.00	0.221	0.71	0.263	0.84	0.902	2.89
Other WBC%	254	9.915	1.416	14.28	0.715	7.21	0.000	0.00	0.241	2.43	1.604	16.18
NEUT%	254	58.90	1.635	2.78	0.411	0.70	0.000	0.00	0.052	0.09	1.687	2.86

Measurand	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
RDW-SD	256	43.02	0.288	0.67	0.000	0.00	0.129	0.30	0.156	0.36	0.352	0.82
RDW-CV	256	14.38	0.097	0.68	0.025	0.17	0.137	0.95	0.073	0.51	0.185	1.28

XW QC CHECK High Level Control

Measurand	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC	256	18.12	0.295	1.63	0.000	0.00	0.141	0.78	0.254	1.40	0.414	2.28
RBC	256	5.324	0.047	0.89	0.019	0.35	0.028	0.52	0.065	1.21	0.087	1.63
HGB	256	17.25	0.142	0.82	0.047	0.27	0.085	0.49	0.180	1.04	0.249	1.44
HCT	256	47.94	0.416	0.87	0.232	0.48	0.353	0.74	0.447	0.93	0.743	1.55
MCV	256	90.06	0.221	0.25	0.230	0.26	0.456	0.51	0.218	0.24	0.598	0.66
MCH	256	32.41	0.398	1.23	0.071	0.22	0.220	0.68	0.461	1.42	0.651	2.01
MCHC	256	35.99	0.434	1.21	0.179	0.50	0.348	0.97	0.427	1.19	0.723	2.01
PLT	256	507.1	9.535	1.88	1.593	0.31	4.705	0.93	12.305	2.43	16.340	3.22
MPV	256	10.06	0.097	0.96	0.071	0.71	0.041	0.40	0.044	0.44	0.134	1.33
LYMPH#	256	6.404	0.144	2.24	0.029	0.45	0.000	0.00	0.163	2.55	0.219	3.42
Other WBC#	256	2.763	0.218	7.90	0.000	0.00	0.053	1.92	0.012	0.42	0.225	8.14
NEUT#	256	8.951	0.254	2.84	0.000	0.00	0.076	0.85	0.083	0.92	0.278	3.11
LYMPH%	256	35.35	0.557	1.58	0.286	0.81	0.000	0.00	0.423	1.20	0.756	2.14
Other WBC%	256	15.25	1.175	7.70	0.000	0.00	0.296	1.94	0.000	0.00	1.211	7.94
NEUT%	256	49.40	1.148	2.32	0.000	0.00	0.195	0.39	0.388	0.78	1.227	2.48
RDW-SD	256	45.57	0.328	0.72	0.156	0.34	0.342	0.75	0.443	0.97	0.667	1.46
RDW-CV	256	14.67	0.186	1.27	0.078	0.53	0.356	2.43	0.317	2.16	0.518	3.53

c. *Linearity*

Linearity of the WBC, RBC, HGB, HCT, and PLT parameters was evaluated using a linearity kit (RANGE CHECK ™ X II – K960557) of known concentrations. The Sysmex XW-100 met the predefined acceptance criteria. The findings of the polynomial regression analysis indicate that the Sysmex XW-100 exhibits linearity across the claimed range.

Parameter	Linearity Performance Specifications
WBC	$1.0–99.9\times10^{3}/\mu L$
RBC	$0.3–7.00\times10^{6}/\mu L$
HGB	0.1–25.0 g/dL
HCT	10.0–60.0%
PLT	$10.0–999\times10^{3}/\mu L$

d. Carryover

Carryover of the Sysmex XW-100 was evaluated by assaying whole blood K_2EDTA samples with high WBC, RBC, HGB, and PLT counts. Three high concentration (H1, H2, and H3) samples were consecutively analyzed followed by three low concentration (L1, L2, L3) samples. Three sets of carryover sequences were run for each type of carryover test on three separate instruments.

Carryover % was determined using the following calculation: % Carryover = (LTV1−LTV3)/(HTV3−LTV3) × 100. The results of the carryover study were within the predefined specifications.

e. Interfering Substances

A verification study was conducted to determine the interference level with the hematology results generated by the Sysmex XW-100 for the following interfering substances: Bilirubin F, Bilirubin C, hemolytic hemoglobin, chyle, and lipids (Intralipid). Six whole blood K_2EDTA tubes were collected from each of the three study subjects. A total of 3 samples were contrived with the specified interferent at various dilutions, mixed, and then analyzed three times.

There was no significant Bilirubin F interference up to a concentration of 37.1 mg/dL for the WBC, RBC, HGB, and PLT parameters. There was no significant bilirubin F interference for HCT up to a concentration of 29.6 mg/dL.

There was no significant Bilirubin C interference up to a concentration of 38.1 mg/dL for the WBC, RBC, HGB, HCT, and PLT parameters.

There was no significant hemolysis interference up to a concentration of 936 mg/dL for the WBC, RBC, HCT, and PLT parameters. There was no significant hemolysis interference up to a concentration of 749 mg/dL for the HGB parameter.

There was no significant Intralipid interference up to a concentration of 55.980 OD for the WBC, RBC, and HCT parameters. There was no significant Intralipid interference up to a concentration of 1.119 OD for the HGB parameter and up to a concentration of 11.196 OD for the PLT parameter.

There was no significant chyle interference up to a concentration of 2579 FTU for the WBC, RBC, HGB, HCT, and PLT parameters.

f. Quality Control Stability

The XW QC CHECK 30-day open-vial stability claim was substantiated by performing three runs over eight time points spanning the 30-day claim utilizing two vials from each of the three QC lots, one operator, and two Sysmex XW-100 analyzers at one internal site.

The 45-day closed-vial stability claim was substantiated by performing three runs over ten time points spanning the 45-day end date claim utilizing two vials from each of the three QC lots, one operator, and two Sysmex XW-100 analyzers at one internal site.

The control vials used in the open and closed-vial stability studies were stored and used in accordance with the instructions for use at room temperature (59–86°F or 15–30°C).

2. Other Supportive Instrument Performance Data Not Covered Above:

a. *Sample Stability*

Whole blood stability was evaluated using a total of 20 (10 normal and 10 abnormal) K_2EDTA whole blood samples on the Sysmex XW-100. The samples were run in triplicate to obtain the baseline on time zero. Single measurements of each sample were subsequently obtained at 8 hours, 12 hours, 24 hours, 36 hours, and 48 hours at room temperature (18–26°C) and refrigerated temperature (2–8°C). The mean percent difference was calculated for each sample and was within the predefined acceptance criteria. Whole blood samples stored at room temperature (59–77° F or 15–25°C) are stable for up to 8 hours and samples stored refrigerated (36–46°F or 2–8° C) are stable for up to 36 hours.

b. *Anticoagulant Comparison (K_2EDTA vs. K_3EDTA)*

Anticoagulant comparison studies were performed to demonstrate comparability between K_2EDTA and K_3EDTA whole blood samples for all reportable parameters. A total of 10 paired whole blood samples (K_2EDTA, K_3EDTA) were collected from study subjects. The samples were run in duplicate on the Sysmex XW-100 and the results of the K_2EDTA samples were compared to the corresponding results of the K_3EDTA sample from the same study subject. The results of the study met the predefined bias limits for all reportable parameters.

Parameter	Unit	K_2EDTA Average Mean Value	K_3EDTA Average Mean Value	Mean Difference	Mean% Difference
WBC	10^3/µL	6.9	6.9	0.0	-0.1
RBC	10^6/ µL	4.96	4.94	0.0	-0.4
HGB	g/dL	13.8	13.7	-0.1	-1.0
HCT	%	43.3	43.0	-0.3	-0.7
MCV	fL	87.4	87.2	-0.2	-0.2
MCH	pg	27.8	27.7	-0.1	-0.4
MCHC	g/dL	31.8	31.7	-0.1	-0.2
PLT	10^3/µL	294	296	1.8	0.6
MPV	fL	10.8	11.0	0.2	1.9
RDW-SD	fL	42.3	42.2	-0.1	-0.2
RDW-CV	%	13.5	13.4	0.0	-0.3

NEUT%	%	62.3	62.2	-0.2	-0.3
LYMPH%	%	29.8	29.7	-0.1	-0.3
Other WBC%	%	7.9	8.0	0.0	0.6
NEUT#	#	2.03	2.03	0.0	0.0
LYMPH#	#	2.03	2.03	0.0	0.0
Other WBC#	#	0.54	0.54	0.0	-0.5

c. *Determination of limit of blank, lower limits of detection and quantitation*

Limit of Blank (LoB) was determined by performing 60 repeat measurements using two blank samples containing XW-Pack D (system diluent). The mean, SD, and LoB were calculated for the WBC, RBC, HGB, HCT, and PLT parameters.

Parameter	Mean	SD	LoB
WBC	0.0 x 10^3/µL	0.0 x 10^3/µL	0.0 x 10^3/µL
RBC	0.0 x 10^6/µL	0.0 x 10^6/µL	0.0 x 10^6/µL
HGB	0.0 g/dL	0.0 g/dL	0.0 g/dL
HCT	0.0%	0.0%	0.0%
PLT	0.0 x 10^3/µL	0.0 x 10^3/µL	0.0 x 10^3/µL

To determine the Limit of Detection (LoD), a total of 60 replicate measurements of three low level samples with target values of 0.3–0.5 x 10^3/µL for WBC, 0.02–0.04 x 10^6/µL for RBC, 0.1–0.4 g/dL for HGB, 0.1–0.3% for HCT, and 10–14 x 10^3/µL for PLT were performed in the whole blood analysis mode.

Limit of Quantitation (LoQ) was determined by using the test results from the LoD study to determine the bias and imprecision for that level of analyte. A total of 45 replicate measurements from three samples (15 measurements per sample) at the lowest concentration for each analyte were performed to verify precision at the low end of the analytical measuring range. The mean, SD, and 2SD were calculated for the WBC, RBC, HGB, HCT, and PLT parameters.

The results of the LoD and LoQ for the Sysmex XW-100™ met the expected lower measuring range for WBC, RBC, HGB, HCT, and PLT.

Parameter	Unit	LoD	LoQ
WBC	10^3/µL	0.1	0.248
RBC	10^6/ µL	0.01	0.014
HGB	g/dL	0.1	0.3
HCT	%	0.1	0.3
PLT	10^3/µL	2	6

d. Reference Intervals

Adult reference intervals for the Sysmex XW-100™ were verified in comparison to the pre-established reference intervals for the Sysmex pocH-100*i* utilizing whole blood samples collected from 121 normal subjects (≥21 years of age).

Parameter	Unit	Male (N=52)	Female (N=64)
		Verified Reference Interval	Verified Reference Interval
WBC	$10^3/\mu L$	4.5-9.9	4.1-9.7
RBC	$10^6/\mu L$	4.02-6.01	3.95-5.61
HGB	g/dL	12.4-17.3	11.4-16.0
HCT	%	37.8-50.7	34.9-47.9
MCV	fL	80.0-94.9	80.9-94.9
MCH	pg	25.9-32.1	26.6-32.2
MCHC	g/dL	32.3-36.2	32.2-35.7
PLT	$10^3/\mu L$	164-343	185-369
MPV	fL	9.4-12.3	9.5-12.3
LYMPH%	%	17.4-50.9	19.6-56.7
Other WBC%	%	1.7-18.3	1.4-14.3
NEUT%	%	44.1-71.1	37.2-71.1
LYMPH#	#	1.0-3.2	1.2-4.1
Other WBC#	#	0.1-1.7	0.1-1.7
NEUT#	#	2.4-5.9	2.6-7.4
RDW-SD	fL	38.9-46.1	38.3-46.0
RDW-CV	%	11.9-14.4	12.0-14.4

A reference range verification study was performed for the infant (N=27), adolescent and transitional adolescent (N=96) pediatric populations by comparing 123 samples collected from pediatric patients ranging from 2 to 21 years of age within each pediatric subcategory shown below. The results of the study verified the pediatric intervals published in Soldin, Brugnara and Wong, *Pediatric Reference Intervals,* AACC Press 6th Edition 2007.

Pediatric Category	Age Range
Child	2 to < 12 years old
Adolescent	12 to < 18 years old
Transitional adolescent	18 to ≤ 21 years old

K. Proposed Labeling:

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

L. Conclusion:

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