510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K210346

B Applicant

Sysmex America, INC.

C Proprietary and Established Names

Sysmex XW-100 Automated 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:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K210346 and CW170012. K210346 was submitted for clearance of a device modification.

B Type of Test:

Complete blood count (WBC, RBC, HGB, HCT, MCV, PLT) and leukocyte 3-part differential (LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#).

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Indication(s) for Use:

The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for in vitro diagnostic use to classify and enumerate the following parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, and NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The XW-100 is intended to be used by operators with a minimum of an earned high school diploma or equivalent.

IV Device/System Characteristics:

A Device Description:

The XW-100 Automated Hematology Analyzer (XW-100) for CLIA Waived Use is an electrical resistance blood cell counter. This technology may also be referred to as Direct Current (DC) or impedance. The XW-100 analyzes human whole blood specimens anticoagulated with K2EDTA or K3EDTA and reports results for 12 hematology parameters, including the basic complete blood count (CBC), 3-part white blood cell (WBC) differential, and MCV.

Principles of Operation

The XW-100 uses direct current with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically. The patient sample is aspirated, measured, diluted with diluent (and lysed for WBC 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. 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. These resistance changes are captured as electric pulses. The various blood cell counts are calculated by counting the pulses that occur in each cell size category. The analyzer then determines blood cell volume and identifies cells by creating and analyzing histograms of the various cell populations using their respective pulse heights. Hemoglobin is measured photometrically using a non-cyanide method.

B Instrument Description Information:

1. Instrument Name:

   XW-100 Automated Hematology Analyzer for CLIA Waived Use

2. Specimen Identification:

   Specimen identification input is manual (by operator).

3. Specimen Sampling and Handling:

   The XW-100 processes anticoagulated venous whole blood collected in K2EDTA or K3EDTA collection tubes. Samples are manually mixed by inversion and loaded into an onboard sample adapter one at a time.

4. Calibration:

   The XW-100 is factory calibrated.

5. Quality Control:

   The XW-100 system performance is evaluated using XW QC CHECK, a stabilized whole blood matrix quality control material designed for statistical process control 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
XW-100 Automated Hematology Analyzer for CLIA Waived Use

B Predicate 510(k) Number(s):
K172604

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210346	K172604
Device Trade Name	XW-100 Automated Hematology Analyzer for CLIA Waived Use	XW-100 Automated Hematology Analyzer for CLIA Waived Use
General Device Characteristic Similarities		
Intended Use/Indications For Use	The XW-100 Automated Hematology Analyzer (XW-100) is a quantitative automated hematology analyzer intended for in vitro diagnostic CLIA waived use to classify and enumerate the following	Same

	parameters for venous whole blood anticoagulated with K2/K3 EDTA: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, and NEUT#. It is not for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases/disorders, oncology patients, critically ill patients, or children under the age of 2.	
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
Mode of Operation	Whole blood mode	Same
Calibration and Quality Control	XW QC CHECK (K143577) SCS™-1000 Calibrator	Same

	(K943268)	
General Device Characteristic Differences		
CLIA Waiver Software Version	Version 1.14 with modification to print suppression rule	Version 1.03

VI Standards/Guidance Documents Referenced:

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

IEC 61010-1, Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements

IEC 61326-1, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 61326-2-6, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Refer to K172604

2. Linearity:

   Refer to K172604

3. Analytical Specificity/Interference:

   Refer to K172604

4. Accuracy (Instrument):

   Refer to K172604 and CW170012

5. Carry-Over:
   Refer to K172604

B Other Supportive Instrument Performance Characteristics Data:

1. Internal study to evaluate new version of software v1.14 with modification to print suppression rule

An internal study was performed to evaluate:

- The effectiveness of the new software version with suppression rule modification to appropriately suppress parameters according to the XW-100 algorithm suppression rules (used to simplify flagging for CLIA waived use).
- The results unsuppressed by the new software and to assess the accuracy of unsuppressed results for all reported parameters.

A total of 139 residual whole blood samples (mix of normal and abnormal) collected in K2EDTA anticoagulant were run on two XW-100 CLIA waived analyzers using the on-market software version (v1.13) and within a target of one hour all samples were run on two additional XW-100 CLIA waived analyzers using the proposed modified software version (v1.14).
The results using both versions of software were compared to assess the frequency of suppression for all parameters, as well as evaluate the comparability of the reported parameters. Deming linear regression analysis was performed on all unsuppressed results for all reported parameters. The results of this regression analysis are shown in the table below.

Internal Study Deming Regression Analysis							
Measurand	**N**	**Result Range (N=139)**	**Correlation Coefficient**	**Slope**	**95% (CI)**	**Intercept**	**95% (CI)**
WBC (x 10^3/µL)	70	3.0–22.8	0.9981	0.9985	0.9792, 1.0178	0.0279	-0.1043, 0.1601
RBC (x 10^6/µL)	129	2.28–5.86	0.9967	1.0086	0.9937, 1.0236	-0.0111	-0.0695, 0.0473
HGB (g/dL)	57	10.2–15.6	0.9874	0.9977	0.9580, 1.0373	0.0145	-0.4867, 0.5157
HCT (%)	58	28.0–47.1	0.9927	1.0030	0.9759, 1.0300	0.1220	-0.9107, 1.1548
PLT (x 10^3/µL)	121	107–570	0.9945	0.9885	0.9657, 1.0113	3.4479	-2.5141, 9.4099
MCV (fL)	58	80.6–108.2	0.9971	1.0024	0.9854, 1.0195	-0.3465	-1.9205, 1.2275
NEUT# (x 10^3/µL)	70	1.1–16.8	0.9978	1.0022	0.9816, 1.0228	-0.0062	-0.1141, 0.1017
NEUT%	70	21.8–91.9	0.9821	1.0126	0.9701, 1.0552	-0.9453	-4.1267, 2.2362
LYMPH# (x 10^3/µL)	70	0.2–8.2	0.9956	0.9740	0.9392, 1.0087	0.04297	-0.0077, 0.0936
LYMPH%	70	1.2–47.5	0.9951	0.9958	0.9717, 1.0200	0.02710	-0.4449, 0.4991
OTHER WBC# (x 10^3/µL)	61	0.1–2.5	0.9098	0.9164	0.6813, 1.1515	0.0648	-0.0962, 0.2258
OTHER WBC %	62	1.2–30.7	0.9129	1.0580	0.9417 to 1.1743	-0.4484	-1.5124 to 0.6156

Conclusion: The results from this study demonstrated that the new version of software is comparable to the prior version of software. Appropriate suppression of results is maintained with the new version of software.

2. Sample challenge study

A prospective study was performed to confirm the appropriate suppression of results with v1.14 software for samples associated with interferences, artifacts, or associated conditions for which results from certain parameters should be suppressed in a CLIA Waived environment. In this study, 173 pre-selected, de-identified leftover K2EDTA venous whole

blood (normal and abnormal) samples were tested on XW-100 CLIA Waived analyzers using software versions v1.03 (K172604 clearance), v1.13 (on-market), or v1.14 (candidate device) by trained operators. The samples were also run on the Sysmex XN-10 analyzer (K112605). Blood smear analysis and WBC differential counts were performed on all samples as a confirmatory method by qualified examiners in accordance with CLSI H20-A2 – *Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition*.
Samples with interfering substances, rare cells, pathologies, or morphologies with emphasis on samples with known conditions to affect RBC indices were specifically targeted for challenge samples. Samples with parameter flags (Alert High and Alert Low) were also evaluated in the study. A list of abnormalities targeted for challenge samples is provided below.

Challenge Samples
Cold Agglutinins
Fragmented RBC's
High Lipids
High WBC Count
Hyperglycemia
Hypernatremia
Hypochromic Anemia
Hyponatremia
Immunoglobulin
Immunosuppressive Drugs
In Vivo Hemolysis
Large and Giant Platelets
Microcytes
Microorganisms (bacterial aggregates, parasites, fungi)
Nucleated RBCs
Platelet Agglutination
Platelet Aggregates
Warm Agglutinins
Other (primarily High MCV, Immature Granulocytes, Atypical Lymphocytes)

Deming linear regression analysis was performed on all unsuppressed results for all reported parameters. The results of this regression analysis are shown in the table below.

Sample Challenge Study Software version v1.03 (K172604) compared to v1.14 (candidate)							
Measurand	**N**	**Result Range (N=173)**	**Correlation Coefficient**	**Slope**	**95% (CI)**	**Intercept**	**95% (CI)**
WBC ($x\ 10^3/\mu L$)	87	3.0–45.9	0.9995	1.0070	0.9922, 1.0218	-0.02695	-0.1549, 0.1010
RBC ($x\ 10^6/\mu L$)	133	2.37–5.71	0.9985	1.0116	1.0013, 1.0218	-0.0118	-0.0497, 0.0261
HGB (g/dL)	91	10.2–18.3	0.9971	1.0053	0.9900, 1.0207	-0.1249	-0.3184, 0.0686
HCT (%)	112	25.0–51.1	0.9982	1.0115	1.0001, 1.0229	0.0794	-0.3247, 0.4834
PLT ($x\ 10^3/\mu L$)	102	104–804	0.9977	1.0045	0.9913, 1.0178	-0.7271	-4.4504, 2.9962
MCV (fL)	112	71.3–111.0	0.9990	1.0188	1.0098, 1.0278	-1.3206	-2.1296, -0.5116
NEUT# ($x\ 10^3/\mu L$)	87	1.7–40.5	0.9993	1.0156	1.0015, 1.0296	-0.0528	-0.1457, 0.0400
NEUT%	87	29.6–97.1	0.9926	0.9761	0.9524, 0.9999	2.0669	0.2159, 3.9179
LYMPH# ($x\ 10^3/\mu L$)	87	0.2–9.4	0.9974	1.0167	0.9876, 1.0459	-0.0029	-0.0472, 0.0412
LYMPH%	87	2.0–66.7	0.9968	0.9938	0.9764, 1.0111	0.2754	-0.0460, 0.5968
OTHER WBC# ($x\ 10^3/\mu L$)	79	0.0–2.2	0.9188	0.9753	0.8721, 1.0785	-0.0272	-0.0975, 0.0430
OTHER WBC %	78	0.7–29.3	0.9523	0.9545	0.8906, 1.0184	-0.1008	-0.6642, 0.4626

Sample Challenge Study Software version v1.13 (on-market) compared to v1.14 (candidate)							
Measurand	**N**	**Result Range (N=173)**	**Correlation Coefficient**	**Slope**	**95% (CI)**	**Intercept**	**95% (CI)**
WBC (x 10^3/µL)	82	3.2–54.4	0.9997	1.0074	0.9979, 1.0169	-0.0206	-0.1118, 0.0705
RBC (x 10^6/µL)	131	2.33–5.73	0.9988	1.0320	1.0228, 1.0412	-0.0655	-0.1006, -0.0303
HGB (g/dL)	83	10.0–17.9	0.9980	1.0228	1.0104, 1.0351	-0.0069	-0.1708, 0.1570
HCT (%)	100	25.3–50.7	0.9982	1.0353	1.0210, 1.0496	-0.4120	-0.9451, 0.1211
PLT (x 10^3/µL)	102	116–821	0.9968	1.0111	0.9896, 1.0326	0.7837	-4.7345, 6.3020
MCV (fL)	100	72.2–110.1	0.9983	1.0485	1.0373, 1.0598	-3.6551	-4.6946, -2.6155
NEUT# (x 10^3/µL)	82	1.6–48.5	0.9995	0.9986	0.9836, 1.0135	0.0603	-0.0437, 0.1643
NEUT%	82	29.3–96.9	0.9911	0.9636	0.9372, 0.9899	3.0143	0.9764, 5.0522
LYMPH# (x 10^3/µL)	82	0.2–9.4	0.9961	1.0062	0.9509, 1.0615	-0.0089	-0.0904, 0.0726
LYMPH%	82	2.1–66.9	0.9963	0.9945	0.9697, 1.0192	-0.0445	-0.4965, 0.4074
OTHER WBC# (x 10^3/µL)	73	0.0–2.1	0.9186	1.0611	0.9086, 1.2136	-0.0526	-0.1476, 0.0424
OTHER WBC %	75	0.4–28.9	0.9462	0.9654	0.8319, 1.0990	0.0311	-0.9067, 0.9690

The results of this study demonstrated that appropriate and expected suppression of results occurred for the XW-100 CLIA Waived analyzer with v1.14 software for challenge samples, as confirmed by blood smear analysis with WBC differential counts and results from the XN-10 analyzer. Regression analysis indicated that the v1.14 software performed similar to the previously cleared software (v1.03, K172604 and CW170012) and software currently on the market (v1.13).

Conclusion: The software change does not impact the appropriate suppression of results for challenging samples and unaffected parameters maintain similar performance to the previously cleared XW-100 CLIA Waived analyzer.

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.