

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number: K060656

B. Purpose for Submission: Traditional 510(k)

C. Manufacturer and Instrument Name: Sysmex America, Inc. Sysmex® XS Automated Hematology Analyzer series (XS-100i and XS-800i).

D. Type of Test or Tests Performed: 21 Complete Blood Count analysis parameters in whole blood.

E. System Descriptions:

1. Device Description: The XS is an automated hematology analyzer which consists of three principal units: (1) Main unit which aspirates, dilutes, mixes and analyzes whole blood samples; (2) Auto Loader on the XS-1000i that supplies samples to the Main Unit automatically ; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system. The XS-1000i and XS-800i are the same instruments except that the XS-1000i has the ability to install an auto loader and the XS-800i uses a manual mode only.
2. Principles of Operation: The XS performs hematology analyses using the following methods: Sheath Flow DC Detection Method, Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin method. Blood cells pass through the aperture of the detector surrounded by a sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain blood cell information. Hemoglobin is measured with the SLS-hemoglobin method using Sodium Lauryl Sulfate, which is an analysis method used in previous Sysmex instrumentation.
3. Modes of Operation: Sampler Mode, Capillary Mode, and Manual Mode with XS-1000i and Manual Mode and Capillary Mode with XS-800i.
4. Specimen Identification: Barcode only with XS-1000i when Sampler is connected.
5. Specimen Sampling and Handling: Sampler Mode, Capillary Mode, and Manual Mode with XS-1000i and Manual Mode and Capillary Mode with XS-800i.

6. Calibration: Automatic and manual calibration using fresh normal blood.
7. Quality Control: Commercial control blood is used and analyzed using X-bar control and L-J (Levy-Jennings) Control programs.
8. Software: Comprehensive software documentation at a Moderate Level of Concern was provided by Sysmex.

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
4. Panel: Hematology (81)

G. Intended Use:

1. Indication(s) for Use: The Sysmex XS is an automated hematology analyzer for in vitro diagnostic use in clinical laboratories.
2. Special Conditions for Use Statement(s): N/A

H. Substantial Equivalence Information

1. Predicate Device Name(s) and 510(k) numbers:
Sysmex XT-Series: K021241, Sysmex XE-2100: K992875
2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	Automated blood cell analyzer.	XT-Series and XE-2100: Same.
Sample Type	Whole Blood	XT-Series and XE-2100: Same

Similarities		
Item	Device	Predicate
Bar Code	Yes	XT-Series and XE-2100: Same

Differences		
Item	Device	Predicate
Sample Volume	20µL, Auto loader mode 20µL, Manual mode 20µL, Capillary dilution	XT-Series: 150µL, Cap piercer mode 85µL, Manual mode 40µL, Capillary dilution XE-2100: 200µL, Cap piercer mode 130µL, Manual mode 40µL, Capillary dilution
Parameters	WBC, Neut%/#, Lymph%/#, Mono%/#, Eos%/#, Baso%/#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV	XT-Series: Same plus: RET%/#, IRF XE-2100: Same plus: NRBC%/#, RET%/#, IRF
Principles	RBC, PLT: DC detection method, WBC: Fluorescent Flow Cytometry-WBC Diff channel using semiconductor laser, HGB: SLS-Hgb method.	XT-Series: RBC, PLT: DC detection method, WBC: Flow Cytometry method using semiconductor laser detection method, HGB: SLS-Hgb method XE-2100: RBC, PLT: Sheath-flow DC detection method, WBC: Flow Cytometry method using semiconductor laser detection method, HGB: SLS-Hgb method.
QC System	L-J: 20 files with 180 points per file.	XT-Series: L-J: 20 files with 300 points per file. XE-2100: L-J: 10 files with 300 points per file.

Differences		
Item	Device	Predicate
# of tests/hour	Approx. 60	XT-Series: Approx 80 XE-2100: Approx 113-150

I. Special Control/Guidance Document Referenced (if applicable): *Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells: final Guidance for Industry and FDA*, issued on December 4, 2001.

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy: Table 1: XS vs. XT*

Parameters	Correlation (r)	Regression (r ²)	Regression Equation	Number of Samples
WBC	1.00	0.9979	y=0.9438x+0.754	609
RBC	1.00	0.9951	y=1.0049x-0.0492	609
HGB	1.00	0.9966	y=1.0119x-0.2155	609
HCT	1.00	0.9941	y=1.0163x-0.7441	609
MCV	0.99	0.9887	y=1.000x+0.2805	609
MCH	0.99	0.9772	y=0.9882+0.3751	609
MCHC	0.95	0.8951	y=0.9459+1.6856	609
PLT	1.00	0.9948	y=0.9885x-4.6694	609
RDW-SD	0.99	0.9784	y=0.9767x+0.8594	607
RDW-CV	0.99	0.9891	y=1.0111x-0.2426	607
MPV	0.82	0.6774	y=0.9247x+0.9571	574
Neut%	1.00	0.9966	y=1.0219x+0.0023	579
Lymph%	1.00	0.9992	y=0.9694x-0.064	581
Mono%	0.98	0.9702	y=0.9792x+0.0584	579
Eos%	0.98	0.9668	y=1.0474x-0.0036	595
Baso%	0.45*	0.2032	y=0.3312x+0.0261	594

*The lower r-value on the basophile% parameter is typically lower than the other parameters due to the low frequency of the basophile cell type.

b.Precision/Reproducibility:

Table 2: Within Run Precision using blood samples (CLSI EP5)

N=20 Samples	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
#1 Mean	8.73	3.93	12.2	37.0	94.2	31.1	33.0	208.1
SD	0.14	0.03	0.1	0.4	1.0	0.2	0.4	3.8
CV%	1.65	0.72	0.6	1.0	1.0	0.6	1.3	1.8
#2 Mean	7.45	4.89	14.8	44.5	91.2	30.3	33.2	223.3
SD	0.13	0.03	0.1	0.4	1.1	0.1	0.4	4.1
CV%	1.74	0.58	0.5	0.8	1.2	0.5	1.3	1.8
#3 Mean	8.22	4.81	13.4	41.1	85.8	27.9	32.6	145.9
SD	0.11	0.02	0.0	0.4	0.8	0.1	0.4	4.3
CV%	1.36	0.38	0.4	0.9	0.9	0.5	1.1	2.9
#4 Mean	7.45	4.50	13.1	40.7	90.5	29.0	32.1	226.3
SD	0.12	0.03	0.1	0.4	1.1	0.2	0.5	3.1
CV%	1.55	0.73	0.5	1.0	1.2	0.7	1.4	1.4
#5 Mean	6.58	3.94	13.2	39.0	99.0	33.4	33.8	382.4
SD	0.13	0.05	0.1	0.5	0.9	0.4	0.4	6.1
CV%	2.03	1.22	0.4	1.3	0.9	1.1	1.3	1.6
Avg CV%	1.67	0.73	0.5	1.0	1.0	0.7	1.3	1.9

- c. *Linearity*: Linearity was evaluated using a series of dilutions of residual patient material. Replicates were measured at each level and represented the range of linearity.

Table 3 Linearity

Parameter	Range Tested	Units	r²	r	Slope	Intercept
WBC	0-1.110	x10 ³ /μL	0.9975	1.00	1.0195	0.0034
	0.080-172.40	x10 ³ /μL	0.9993	1.00	1.0103	0.3659
	0.015-448.63	x10 ³ /μL	0.9997	1.00	0.9963	1.0965
RBC	0—8.93	x10 ⁶ /μL	0.999	1.00	1.0096	0.0393
HGB	0—26.4	g/dL	0.9992	1.00	1.0132	0.0009
HCT	0—74.9	%	0.9959	1.00	1.0999	0.7802
	0.4—64.9	%	0.9919	1.00	1.0103	1.7469
PLT	0—117	x10 ³ /μL	0.9997	1.00	0.9949	1.3913
	3--5670	x10 ³ /μL	0.9981	1.00	0.9876	-41.069

- d. *Carryover*:

Carryover was evaluated by assaying a sample with high concentration three consecutive times followed immediately by testing a low sample consecutively 3 times. This is the method in *Guidelines for the valuation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications*. ISLH, January 14, 1994.

Table 4: Carryover

Parameter	% Carryover	% Carryover	Manufacturer Specifications
WBC	0.01	-0.02	≤1%
RBC	0.00	-0.21	≤1%
HGB	0.00	0.59	≤1%
HCT	0.00	0.00	≤1%
PLT	0.05	0.00	≤1%

e. *Interfering Substances:*

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

Reference Values: Normal specimens from this study fell within these ranges.

Table 5: XS Reference Range Verification

Parameter	Females n=133	Males n=182	Units
WBC	3.98-10.04	4.23-9.07	$\times 10^3/\mu\text{L}$
Neut%	34.0-71.1	34.0-67.9	%
Lymph%	19.3-51.7	21.8-53.1	%
Mono%	4.7-12.5	5.3-12.2	%
Eo%	0.7-5.8	0.8-7.0	%
Baso%	0.1-1.2	0.2-1.2	%
Neut#	1.56-6.13	1.78-5.38	$\times 10^3/\mu\text{L}$
Lymph#	1.18-3.74	1.32-3.57	$\times 10^3/\mu\text{L}$
Mono#	0.24-0.36	0.30-0.82	$\times 10^3/\mu\text{L}$
Eo#	0.04-0.36	0.04-0.54	$\times 10^3/\mu\text{L}$
Baso#	0.01-0.08	0.01-0.08	$\times 10^3/\mu\text{L}$
RBC	3.93-5.22	4.63-6.08	$\times 10^6/\mu\text{L}$
HGB	11.2-15.7	13.7-17.5	g/dL
HCT	34.1-44.9	40.1-51.0	%
MCV	79.4-94.8	79.0-92.2	fL
MCH	25.6-32.2	25.7-32.2	pg
MCHC	32.2-35.5	32.3-36.5	g/dL
RDW-CV	11.7-14.4	11.6-14.4	%
RDW-SD	36.4-46.3	35.1-43.9	fL
PLT	182-369	163-337	$\times 10^3/\mu\text{L}$

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.

