510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____.

Submitter's name, address, telephone number, a contact person, and date the summary was prepared:

Submitter's Name: Sysmex America, Inc.

Submitter's Address: 577 Aptakistic Road
Lincolnshire, IL 60069

Submitter's Telephone: (224) 543-9618

Submitter's FAX: (224) 543-9699

Submitter's Contact: Sharita Brooks

Date 510(k) Prepared: February 27, 2021

Name of the device, including the trade or proprietary name, the common or usual name, and the classification name:

Proprietary Name: Sysmex® XN-10 Automated Hematology Analyzer

Common Name: Automated Hematology Analyzer

Regulation Description: Automated Differential Cell Counter

Regulation Section: 21 CFR 864.5220

Device Class: 2

Product Code: GKZ

Related Items:

Product Code: 81GIF
CELLPACK® DCL (Diluent)
CELLPACK® DFL (Diluent)
CELLPACK® DFL (Diluent)

Product Code: 81GGK
SULFOLYSER® (Lyse)
Lysercell™ WDF (Lyse)
Lysercell™ WNR (Lyse)

Product Code: 81KJK
Fluorocell™ WDF (Stain)
Fluorocell™ RET (Stain)
Fluorocell™ WNR (Stain
Fluorocell™ PLT (Stain)

Product Code: 81KSA
XN CAL™ (Calibrator)
XN CAL PF™ (Calibrator)

Product Code: 81JPK
XN CHECK™ (Control)
XN CHECK™ BF (Control)
Plt-CHECK™ (Control)

Product Code: 81JCB
CELLCLEAN™ AUTO

Primary Predicate Device and 510(k) number:

Sysmex XE-2100D Automated Hematology Analyzer, BK080067

Secondary Predicate Device and 510(k) number:

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

Description of the Device:

Sysmex XN-10 is a quantitative multi-parameter automated hematology analyzer intended to perform tests on whole blood samples collected in K_2 or K_3EDTA and body fluids (pleural, peritoneal and synovial) collected in K_2 EDTA anticoagulant. The analyzer also performs tests on cerebrospinal fluid (CSF) that is not collected in anticoagulant.

The XN-10 Blood Bank mode can also be used in blood processing centers for QC release testing of post-processed components. The blood bank analysis mode enumerates RBC, HGB and HCT parameters for red blood cell components with anticoagulants (CPD, CP2D, ACD-A, CPDA-1) and PLT for platelet components with anticoagulants (CPD, ACD-A).

The XN-10 Analyzer performs analysis using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin. The RF/DC detection method detects the size of the cells by changes in direct-current resistance and the density of the cell interior by changes in radio-frequency resistance. Cells pass through the aperture of the detector surrounded by sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the cells passing through the flow cell. The forward scattered light is received by the photodiode; 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 cell information. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The system carries out all processes automatically from aspiration of the sample to outputting results and uses Microsoft Windows Operating System.

Statement of Intended Use:

The Sysmex XN-10 Automated Hematology Analyzer is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-10 classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IPF, 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 K_2 or K_3EDTA anticoagulant and, serous and synovial fluids in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

The XN-10 Blood Bank mode is intended for use in blood processing centers for QC release testing of post-processed components. The Blood Bank mode enumerates RBC, HGB and HCT

parameters for red blood cell components with anticoagulants (CPD, CP2D, ACD-A, CPDA-1) as well as PLT for platelet components with anticoagulants (CPD, ACD-A).

Summary of Substantial Equivalence:

Sysmex XN-10 Automated Hematology Analyzer is a module cleared in K112605 as part of the XN-Series (XN-10, XN-20). Sysmex XN-10 Automated Hematology Analyzer is the same as the XN-10 Analyzer except for an expanded intended use achieved with the addition of a Blood Bank mode.

The proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode has a similar intended use and operates with similar scientific technology as the predicate device, Sysmex XE-2100D Automated Hematology.

Table 5-1 compares the proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode to the predicate device, Sysmex XE-2100D Automated Hematology Analyzer (BK080067).

Table 5-1. Comparison of Subject Device and Predicate Device

Item	Subject Device	Primary Predicate Device (BK080067)
Similarities		
Brand Name	Sysmex XN-10 Automated Hematology Analyzer	Sysmex XE-2100D Automated Hematology Analyzer
Common Name	Differential Cell Counter	Differential Cell Counter
Product Code	GZK; 21 CFR 864.5220	GZK; 21 CFR 864.5220
Intended Use	The Sysmex XN-10 Automated Hematology Analyzer is a quantitative multi-parameter automated hematology analyzer intended for in *vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-10 classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IPF, 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	The Sysmex XE-2100D, Automated Hematology Analyzer, is intended for in vitro diagnostic use in clinical laboratories and donor centers as a multi-parameter hematology analyzer using EDTA anticoagulant and in blood processing centers for QC release testing of post processed components using anticoagulants (CPD, CP2D, ACD-A, CPDA-1)commonly used in non-whole blood products for red blood cell components (CP2D, ACD-A, CPDA-1, CPD) for RBC, HGB and HCT parameters and platelet components (CPD and ACD-A) for PLT and MPV parameters.

	in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood, should be collected in K_2 or K_3EDTA anticoagulant and, serous and synovial fluids in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended. The XN-10 Blood Bank mode is intended for use in blood processing centers for QC release testing of post-processed components. The Blood Bank mode enumerates RBC, HGB and HCT parameters for red blood cell components with anticoagulants (CPD, CP2D, ACD-A, CPDA-1) as well as PLT for platelet components with anticoagulants (CPD, ACD-A).	
Parameters	**RBC Component Bags:** RBC Red Blood Cell Count HGB Hemoglobin HCT Hematocrit **PLT Component Bags:** Platelet Count	**RBC Component Bags:** RBC Red Blood Cell Count HGB Hemoglobin HCT Hematocrit **PLT Component Bags:** PLT Platelet Count
Test Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method	Performs hematology analyses according to RF/Detection method, Flow Cytometry methods using a semiconductor laser and SLS-hemoglobin method
Sample Type	CPD, CP2D, ACD-A, CPDA-1 anticoagulants used in (Non-Whole Blood) RBC and PLT Component Bags	CPD, CP2D, ACD-A, CPDA-1 anticoagulants used in (Non-Whole Blood) RBC and PLT Component Bags
Controls	Plt-CHECK- 2 levels	Plt-CHECK- level 2

Item	Subject Device	Primary Predicate Device (BK080067)
Differences		
Parameters	N/A	**PLT Component Bags:** MPV Mean Platelet Volume
Reagents	CELLPACK DCL(Diluent) CELLPACK DFL (Diluent) SULFOLYSER (Lyse) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse) FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain) CELLCLEAN	CELLSHEATH ™ (Diluent) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) SULFOLYSER (Lyse) CELLPACK™ (Diluent) STROMATOLYSER-FB™ (Lyse)
Reportable Range	RBC: 0.01 to 8.60 x 10^6/µL HGB: 0.0 to 26.0 g/dL HCT: 0.1 to 75.0% PLT: 2 to 5000 x 10^3/µL	RBC: 0.00 – 8.00 x 10^6/µL HGB: 0.0 – 25.0 g/dL HCT: 0.0 – 75.0% PLT: 0 – 5000 x 10^3/µL
Controls	XN CHECK – 3 levels	e-CHECK – 3 levels
Calibrator	XN CAL XN CAL PF	X CAL

Discussion of Similarities and Differences:

The subject device, Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode, shares many similarities with the predicate device, Sysmex XE-2100D Automated Hematology Analyzer. It has a similar intended use as the predicate device and the testing principles have the same fundamental scientific technology. The XN-10 Blood Bank mode enumerates the same RBC, HGB and HCT parameters for red blood cell components and same PLT parameter for platelet components as the predicate device. The subject device also utilizes the same platelet control material as the predicate device (*plt*-CHECK).

The subject device also utilizes different reagents, controls and calibrators and has a slightly different reportable range for parameters RBC, HGB, HCT and PLT than the predicate device to achieve the same intended use.

In order to demonstrate that differences in technological characteristics between the subject device and predicate device do not impact safety and effectiveness, the following clinical performance studies were conducted on the proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode: Accuracy, Precision (Reproducibility), Mixing Study, Sample Stability, and Linearity.

Summary of Performance Data:

A summary of the performance data from the method comparison study (accuracy), precision (reproducibility), linearity, sample stability and mixing study conducted on the XN-10 Blood Bank mode to demonstrate substantial equivalence to the XE-2100D Automated Hematology Analyzer is provided below:

Method Comparison - Blood Bank mode

Table 5-2. Correlation and Estimated Bias (RBC and PLT Components – All Combined Sites) XE-2100D vs. XN-10 Blood Bank Mode

Parameter	Component Type	N	Result Range	Correlation Coefficient[1]	Slope (95% CI)	Intercept (95% CI)	Mean Diff	Mean %Diff
RBC ($x\ 10^6$/uL)	RBC Component	416	3.74 - 8.55	0.9941	1.060 (1.049, 1.071)	-0.353 (-0.421, -0.286)	0.020	0.28
HGB (g/dL)			11.3 - 23.2	0.9944	0.997 (0.987, 1.008)	-0.107 (-0.299, 0.086)	-0.16	-0.83
HCT (%)			35.3 - 73.3	0.9750	1.012 (0.991, 1.033)	-0.527 (-1.803, 0.749)	0.20	0.34
PLT ($x\ 10^3$/uL)	PLT Component	359	562 - 2928	0.9835	1.016 (0.994, 1.039)	-12.651 (-43.874, 18.573)	12.2	0.84

Precision (Reproducibility) - Blood Bank mode

Table 5-3. Whole Blood Reproducibility (All Instruments Combined)

XN-10 Blood Bank Mode				Within Run		Between Run		Between Day		Between Instrument		Total Imprecision		Acceptance Criteria Limit %CV	PASS/FAIL
Measurand	Control Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV		
RBC (10^6/µL)	XN CHECK Level 1	60	2.361	0.0179	0.76	0.0000	0.00	0.0201	0.85	0.0437	1.85	0.0513	2.17	3.9	PASS
	XN CHECK Level 2	60	4.212	0.0287	0.68	0.0174	0.41	0.0309	0.73	0.0838	1.99	0.0954	2.27	3.4	PASS
	XN CHECK Level 3	60	4.905	0.0384	0.78	0.0000	0.00	0.0312	0.64	0.0896	1.83	0.1023	2.09	3.5	PASS
HGB (g/dL)	XN CHECK Level 1	60	5.91	0.043	0.72	0.000	0.00	0.047	0.79	0.106	1.80	0.124	2.09	4.3	PASS
	XN CHECK Level 2	60	11.48	0.064	0.56	0.019	0.16	0.090	0.78	0.224	1.95	0.250	2.18	3.6	PASS
	XN CHECK Level 3	60	14.69	0.067	0.46	0.048	0.33	0.118	0.81	0.266	1.81	0.302	2.06	3.8	PASS
HCT (%)	XN CHECK Level 1	60	17.43	0.144	0.82	0.046	0.26	0.233	1.33	0.269	1.54	0.386	2.21	5.3	PASS
	XN CHECK Level 2	60	33.21	0.237	0.71	0.153	0.46	0.320	0.96	0.528	1.59	0.679	2.04	4.6	PASS
	XN CHECK Level 3	60	41.79	0.350	0.84	0.150	0.36	0.369	0.88	0.523	1.25	0.745	1.78	4.8	PASS
PLT (10^3/µL)	XN CHECK Level 3	60	545.4	4.15	0.76	1.98	0.36	3.71	0.68	2.68	0.49	6.49	1.19	19.2	PASS
	Plt CHECK Level 1	60	1628.3	10.91	0.67	8.09	0.50	5.35	0.33	8.12	0.50	16.70	1.03	13.3	PASS
	Plt CHECK Level 2	60	3101.8	20.98	0.68	13.72	0.44	18.59	0.60	4.14	0.13	31.48	1.01	12.5	PASS

Linearity - Blood Bank mode

Table 5-4. Yield Parameters

Site	Parameter	Final Linear Best-Fit Mode			Dilution Relative % Bias		# Dilution (Range)
		R-squared (adjusted)	Slope (SE)[2]	Intercept (SE)[2]	Maximum Observed[1]	Acceptance Criterion[3]	
Internal Site SN16366	HCT (%)	0.9981	0.9765 (0.0160)	0.4259 (0.5928)	0.00%	±3%	8 (0.00 to 69.70)
	HGB (g/dL)	0.9977	0.9685 (0.0176)	0.1684 (0.2302)	0.00%	±2%	8 (0.00 to 24.37)
	PLT (10^3/µL)	0.9999	0.9973 (0.0029)	-5.6938 (8.4489)	0.00%	±5%	10 (2.0 to 6692.7)
	RBC (10^6/µL)	0.9982	0.9824 (0.0158)	0.0442 (0.0732)	0.00%	±2%	8 (0.000 to 8.723)
Internal Site SN42666	HCT (%)	0.9973	1.0073 (0.0198)	0.0774 (0.7340)	0.00%	±3%	8 (0.00 to 72.83)
	HGB (g/dL)	0.9965	1.0072 (0.0224)	0.0003 (0.2923)	0.00%	±2%	8 (0.00 to 25.83)
	PLT (10^3/µL)	1.0000	1.0011 (0.0015)	-0.7433 (4.4066)	0.00%	±5%	10 (1.0 to 6727.0)
	RBC (10^6/µL)	0.9972	1.0071 (0.0200)	0.0183 (0.0926)	0.00%	±2%	8 (0.000 to 9.053)
Internal Site SN42687	HCT (%)	0.9980	0.9955 (0.0169)	0.0636 (0.6256)	0.00%	±3%	8 (0.00 to 71.97)
	HGB (g/dL)	0.9979	0.9966 (0.0174)	0.0089 (0.2269)	0.00%	±2%	8 (0.00 to 25.33)
	PLT (10^3/µL)	1.0000	1.0009 (0.0021)	1.0351 (6.2755)	0.00%	±5%	10 (1.0 to 6733.0)
	RBC (10^6/µL)	0.9981	1.0063 (0.0167)	0.0054 (0.0773)	0.00%	±2%	8 (0.000 to 9.037)

Sample Stability - Blood Bank mode

Table 5-5. RBC Component Sample Stability at Refrigerated Temperature

Component Type	Anticoagulant (Additive)	Parameter	Units	Mean (n=11)	Mean %Difference (Between baseline and Mean Measurement)	Controlled Refrigerated Temperature (LT) (1-6°C or 33.8-42.8°F) At 48 Hours
RBC	CPD (AS-1, AS-5)	RBC	x 10^6/µL	6.90	0.9	48 hours
		HGB	g/dL	20.6	0.5	48 hours
		HCT	%	63.7	0.6	48 hours

Table 5-6. PLT Component Sample Stability at Room Temperature

Component Type	Anticoagulant (Additive)	Parameter	Units	Mean (n=11)	Mean %Difference (Between baseline and Mean Measurement)	Controlled Room Temperature (RT) (20-24°C or 68.0-75.2°F) At 24 Hours
PLT	ACD-A (none)	PLT	x 10^3/µL	1376	-1.7%	24 hours

Mixing Study - Blood Bank mode

Table 5-7. RBC and PLT Component Samples Mixing Study

Yield Parameters XN-10 Blood Bank Mode			Baseline	Run 1	Run 2	Run 1 - Baseline		Run 2 - Baseline		Mean %Diff Limits	PASS/ FAIL
Component Type (Anticoagulant/ Additive)	**Parameter**	**N**	**Mean (SD) [%CV]**	**Mean (SD) [%CV]**	**Mean (SD) [%CV]**	**Mean Diff.**	**Mean %Diff.**	**Mean Diff.**	**Mean %Diff.**		
RBC Component (CPD-AS-5)	RBC ($10^6/\mu L$)	10	6.476 (0.0422) [0.65%]	6.479 (0.0256) [0.39%]	6.467 (0.0460) [0.71%]	0.003	0.04	-0.009	-0.13	±2.0%	PASS
	HGB (g/dL)		20.75 (0.108) [0.52%]	20.82 (0.092) [0.44%]	20.80 (0.047) [0.23%]	0.070	0.33	0.05	0.24	±2.5%	PASS
	HCT (%)		64.14 (0.502) [0.78%]	64.27 (0.206) [0.32%]	64.18 (0.480) [0.75%]	0.130	0.20	0.04	0.06	±2.0%	PASS
PLT Component (Not Available)	PLT ($10^3/\mu L$)		1567.2 (8.97) [0.57%]	1568.7 (6.22) [0.40%]	1574.2 (7.63) [0.48%]	1.5	0.09	7.0	0.44	±7.0%	PASS

The results of the performance testing demonstrated that pre-determined acceptance criteria were met and no new issues of safety or effectiveness were identified.

Conclusion:

The proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode and its predicate device, Sysmex XE-2100D Automated Hematology Analyzer, have the same intended use, fundamental technology, principles of operation, and comparable performance characteristics. Performance, verification, and validation testing were conducted to evaluate substantial equivalence to the predicate device. The results of this testing demonstrate that pre-determined acceptance criteria were met and no new issues of safety or effectiveness were identified. Therefore, the proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode is substantially equivalent to the predicate device, Sysmex XE-2100D Automated Hematology Analyzer.