BK210631

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:

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Date 510(k) Prepared: April 20, 2022

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:

BD LeucoCOUNT Reagent (BK970046)

BD FACSCalibur Flow Cytometry System (K923790)

Secondary Predicate Device and 510(k) number:

Sysmex XN-Series (XN-10) Automated Hematology Analyzer, BK210559

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 Blood Bank mode also performs residual WBC counts on leukoreduced red blood cell and platelet components.

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). The Blood Bank mode also performs residual WBC counts on leukoreduced red blood cell and platelet components.

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). The intended use of the Sysmex XN-10 Automated Hematology Analyzer was expanded in submission number BK210559 to achieve the addition of a Blood Bank mode for yield parameters (RBC, HGB, HCT and PLT).

The proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode residual WBC parameter has a similar intended use and operates with similar scientific technology as the predicate devices, BD FACSCalibur Flow Cytometer System using the BD LeucoCOUNT Reagent for residual WBC (rWBC).

Table 5-1 compares the proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode to the predicate devices, BD FACSCalibur Flow Cytometer System using the BD LeucoCOUNT Reagent.

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

Item	**Subject Device** Sysmex XN-10 Automated Hematology Analyzer	**Primary Predicate Devices** BD FACSCalibur Flow Cytometer System (K923790) BD LeucoCOUNT Reagent (BK970046)
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,	The BD FACSCalibur Flow Cytometer identifies and enumerates lymphocyte subsets in human cells in suspension. The BD LeucoCOUNT™ consists of BD LeucoCOUNT™ reagent (propidium iodide fluorescent dye) and BD Trucount™ tubes and is intended for use with the BD FACSCalibur™, BD FACSort™, BD FACScan™, and

	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). The Blood Bank mode also performs residual WBC counts on leukoreduced red blood cell and platelet components.	BD FACSVia™ flow cytometer systems, or for a flow cytometer equipped with a 488-nm argon ion laser able to threshold on FL2, for enumerating residual white blood cells (rWBCs) in leucoreduced blood products. The BD Leucocount™ RBC Control Kit Consists of Red Blood Cells (RBC) Low and RBC High process controls intended for use with the BE BD lLeucocountCOUNT Kit Reagent to monitor the process for enumeration of residual leucocytes in leucoreduced RBC products including dilution, staining, instrument set up and white blood cell (WBC) enumeration. The BD LeucoCOUNT™ PLT Control Kit Consists of Platelet (PLT) Low and PLT High process controls intended for use with the BD LeucoCOUNT Reagent to monitor the process for enumeraton of residual leucocytes in leucoreduced Platelet products including dilution, staining, instrument set up and white blood cell (WBC) enumeration.
Similarities		
Item	**Subject Device** Sysmex XN-10 Automated Hematology Analyzer	**Primary Predicate Devices** BD FACSCalibur Flow Cytometer System (K923790) BD LeucoCOUNT Reagent (BK970046)
Common Name	Differential Cell Counter	Differential Cell Counter
Product Code	GKZ; 21 CFR 864.5220	GKZ; 21 CFR 864.5220
Parameters	**RBC Component Bags:** WBC White Blood Cell Count **PLT Component Bags:**	Same

	WBC White Blood Cell Count	
Sample Type	CPD, CP2D, ACD-A, CPDA-1 anticoagulants used in (Non-Whole Blood) RBC and PLT Component Bags	Same
Differences		
Item	**Subject Device** Sysmex® XN-10 Automated Hematology Analyzer	**Primary Predicate Devices** BD FACSCalibur Flow Cytometer System (K923790) BD LeucoCOUNT Reagent (BK970046)
Test Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.	Flow cytometry using dual-laser technology (air-cooled argon laser and a red diode laser), interbeam compensation, multicolor capability and an alignment free optical design. BD Trucount tubes making a single-platform for absolute counting.
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	BD MultiTEST™ BD Tritest™ BD LeucoCOUNTTM rWBC enumeration Kit Sheath: BD FACSFlow™ sheath fluid Clean: BD FACSF™ Clean or 10% household bleach Rinsing: BD FACSF™ shutdown solution or deionized (DI) water Waste decontamination full-strength bleach TruCount tubes
Reportable Range	WBC: 0.0020 to 0.3500 x 10^3/µL	WBC: 0 to 300 cells/µL
Controls	XN CHECK BF – 2 levels	BD LeucoCOUNT™ RBC Control Kit – 2 Levels BD LeucoCOUNT™ PLT Control Kit – 2 Levels BD Multi-Check controls
Calibrator	XN CAL XN CAL PF	BD CaliBRITE™ beads

Discussion of Similarities and Differences:

The subject device, Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode, shares many similarities with the predicate devices, BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent. It has a similar intended use as the predicate devices and the testing principles have similar fundamental scientific technology. The XN-10 Blood Bank mode enumerates the same WBC parameter for leukoreduced red blood cell components and platelet components as the predicate devices.

The subject device also utilizes different reagents, controls and calibrators and has a slightly different reportable range for parameter WBC than the predicate devices to achieve the same intended use.

In order to demonstrate that differences in technological characteristics between the subject device and predicate devices 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 for the residual WBC parameter: Accuracy, Precision (Reproducibility, Repeatability), Sample Stability, Linearity and Detection Limits (LoB, LoD and LoQ).

Summary of Performance Data:

A summary of the performance data from the method comparison study (accuracy), precision (reproducibility, repeatability), linearity, sample stability and detection limits conducted on the XN-10 Blood Bank mode residual WBC parameter to demonstrate substantial equivalence to the BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent for residual WBC parameter is provided below:

Method Comparison - Blood Bank mode

Table 5-2: Correlation and Estimated Bias (RBC and PLT Components – All Instruments Combined) BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent vs. XN-10 Blood Bank Mode residual WBC

Component Type	Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
RBC	WBC (x 10^3/uL)	467	0.0000 to 0.6019	0.9703	0.9843 (0.8922, 1.0764)	-0.0008 (-0.0029, 0.0013)
PLT		465	0.0000 to 0.5696	0.9862	0.9523 (0.8747, 1.0299)	0.0001 (-0.0013, 0.0017)

Table 5-2-1: Correlation and Estimated Bias (RBC and PLT Components – All Instruments Combined) BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent vs. XN-10 Blood Bank Mode residual WBC at QC Cut-off for leukoreduction (range 0.0051 – 0.0200 x 10^3/µL)

QC Cut-off Range						
Component Type	Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept(95% CI)
RBC	WBC (x 10^3/uL)	66	0.0022 to 0.0197	0.8221	0.9192 (0.7359, 1.1026)	-0.00007 (-0.0010, 0.0008)
PLT		89	0.0021 to 0.0199	0.9151	1.0614 (0.9412, 1.1817)	-0.00151 (-0.00244, -0.00058)

Precision (Reproducibility) - Blood Bank mode

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

XN-10 Blood Bank Mode residual WBC				Within Run		Between Run		Between Day		Between Instrument		Total Imprecision		Acceptance Criteria (%CV)	PASS/ FAIL
Measurand	**Sample Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**		
WBC ($10^3/\mu L$)	Low	60	0.00742	0.000704	9.48	0.000000	0.00	0.000092	1.23	0.000000	0.00	0.000710	9.56	±20.0%	PASS
	Medium	60	0.01459	0.000793	5.44	0.000000	0.00	0.000000	0.00	0.000303	2.08	0.000849	5.82		PASS
	High	60	0.07111	0.002400	3.38	0.000000	0.00	0.001409	1.98	0.002595	3.65	0.003805	5.35		PASS

Precision (Repeatability) - Blood Bank mode

Table 5-4. Whole Blood Reproducibility (All Instruments Combined) – residual WBC

Parameter	Component Type	Target Range	Instrument	N	Mean	SD	%CV	Range	Limit CV%
WBC (10^3/uL)	Platelet Component	0.0000 to < 0.0020	16366	10	0.000110	0.0000876	79.60%	0.00000 - 0.00030	NA*
			22409	10	0.000480	0.0002201	45.85%	0.00020 - 0.00080	
			23987	10	0.000250	0.0001080	43.20%	0.00010 - 0.00040	
			42666	10	0.000180	0.0000632	35.14%	0.00010 - 0.00030	
		0.0020 to < 0.0050	16366	10	0.003450	0.0003206	9.29%	0.00300 - 0.00400	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.002090	0.0003107	14.87%	0.00150 - 0.00250	
			23987	10	0.001830	0.0002263	12.37%	0.00150 - 0.00230	
			42666	10	0.003510	0.0004408	12.56%	0.00250 - 0.00420	
		0.0050 to < 0.0200	16366	10	0.011740	0.0009383	7.99%	0.01030 - 0.01330	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.017230	0.0013309	7.72%	0.01550 - 0.01980	
			23987	10	0.017670	0.0009911	5.61%	0.01630 - 0.01980	
			42666	10	0.012140	0.0004477	3.69%	0.01140 - 0.01280	
		0.0200 to 0.3500	16366	10	0.131580	0.0038525	2.93%	0.12650 - 0.13920	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.212830	0.0053408	2.51%	0.20470 - 0.22120	
			23987	10	0.210780	0.0031435	1.49%	0.20720 - 0.21550	
			42666	10	0.132030	0.0027933	2.12%	0.12720 - 0.13630	

Parameter	Component	Target Range	Instrument	N	Mean	SD	%CV	Range	Limit CV%
WBC (10^3/uL)	RBC Component	0.0000 to < 0.0020	16366	10	0.001020	0.0003706	36.33%	0.00050 - 0.00180	NA*
			22409	10	0.001440	0.0003062	21.27%	0.00090 - 0.00190	
			23987	10	0.001290	0.0001370	10.62%	0.00100 - 0.00150	
			42666	10	0.000720	0.0003084	42.83%	0.00020 - 0.00130	
		0.0020 to < 0.0050	16366	10	0.004290	0.0005877	13.70%	0.00340 - 0.00530	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.002730	0.0003713	13.60%	0.00230 - 0.00340	
			23987	10	0.002850	0.0004428	15.54%	0.00230 - 0.00390	
			42666	10	0.004630	0.0004572	9.87%	0.00360 - 0.00520	
		0.0050 to < 0.0200	16366	10	0.013590	0.0007695	5.66%	0.01190 - 0.01450	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.007460	0.0006518	8.74%	0.00630 - 0.00840	
			23987	10	0.008150	0.0006451	7.91%	0.00740 - 0.00970	
			42666	10	0.013230	0.0007704	5.82%	0.01210 - 0.01460	
		0.0200 to 0.3500	16366	10	0.159470	0.0031184	1.96%	0.15500 - 0.16340	≤20.0% (WBC ≥0.0020 x 10^3/µL)
			22409	10	0.233140	0.0035119	1.51%	0.22800 - 0.23920	
			23987	10	0.234060	0.0041479	1.77%	0.22890 - 0.24090	
			42666	10	0.161460	0.0020051	1.24%	0.15890 - 0.16420	

*NA – Not applicable for concentrations below AMR.

Linearity - Blood Bank mode

Table 5-5. Whole Blood - rWBC

Site	Parameter	Final Linear Best-Fit Mode			Dilution Relative % Bias		#Dilution (Range)
		R-squared (adjusted)	Slope (SE)	Intercept (SE)	Maximum Observed	Acceptance Criterion	
Internal Site SN16366	WBC (10^3/µL)	0.9984	0.9780 (0.0103)	-0.0032 (0.0014)	0.00%	<0.0020 within ±1.60 cells/µL 0.0020-0.0050 within ±44.0% or ±1.60 (x10^3/µL) 0.0051-0.0200 within ±15.0% or ±1.75 (x10^3/µL) 0.0210-0.0300 within ±7.5% or ±2.00 (x10^3/µL) 0.0310-0.3500 within ±3.0% or ±5.25 (x10^3/µL) >0.3500 within ±3.0% or ±14.00 (x10^3/µL)	15 (0.00000 to 0.36860)
Internal Site SN42666	WBC (10^3/µL)	0.9988	0.9643 (0.0089)	-0.0034 (0.0012)	0.00%		15 (0.0000 to 0.36360)
Internal Site SN42687	WBC (10^3/µL)	0.9987	0.9986 (0.0094)	-0.0021 (0.0013)	0.00%		15 (0.00000 to 0.36877)

Sample Stability - Blood Bank mode

Table 5-6: RBC and PLT Component Sample Stability near QC Cut-off for leukoreduction (range 0.0051 – 0.0200 x 10^3/µL) - rWBC

XN-10 Blood Bank Mode (Residual cell count)						Mean Relative Difference (Mean Difference)				Stability Acceptance Criteria
Temperature	Parameter	Component Type	N	Range	Baseline Mean	24 Hours	48 Hours	72 Hours	73 Hours	
Refrigerated Temperature (1-6°C or 33.8-48.8°F)	WBC (10^3/µL)	RBC	5	0.0051 to 0.0195	0.01222	18.2% (0.00223)	9.8% (0.00120)	13.8% (0.00169)	9.8% (0.00120)	Within ± 21.6% or ±0.00234
Room Temperature (20-24°C or 68.0-75.2°F)	WBC (10^3/µL)	RBC	6	0.0044 to 0.0212	0.01303	4.7% (0.00061)	-20.2% (-0.00263)	-27.2% (-0.00354)	-25.9 (-0.00338)	
Room Temperature (20-24°C or 68.0-75.2°F)	WBC (10^3/µL)	PLT	4	0.0028 to 0.0203	0.01269	-4.2% (-0.00054)	-18.6% (-0.00236)	-24.1% (-0.00306)	-27.3% (-0.00346)	

Table 5-6-1: RBC and PLT Component Sample Stability Across Reportable Range (range 0.0020 – 0.3500 x 10^3/µL) - rWBC

XN-10 Blood Bank Mode (Residual cell count)						Mean Relative Difference (Mean Difference)				Stability Acceptance Criteria
Temperature	Parameter	Component Type	N	Range	Baseline Mean	24 Hours	48 Hours	72 Hours	73 Hours	
Refrigerated Temperature (1-6°C or 33.8-48.8°F)	WBC (10^3/µL)	RBC	15	0.0051 to 0.2976	0.09473	0.7% (0.00068)	-4.3% (-0.00406)	-7.5% (-0.00714)	-8.2% (-0.00778)	Within ± 15% or ± 0.00175
Room Temperature (20-24°C or 68.0-75.2°F)	WBC (10^3/µL)	RBC	15	0.0044 to 0.2952	0.09513	-3.7% (-0.00356)	-14.4% (-0.01368)	-22.8% (-0.02172)	-22.8% (-0.02171)	
Room Temperature (20-24°C or 68.0-75.2°F)	WBC (10^3/µL)	PLT	15	0.0028 to 0.3011	0.09428	-2.0% (-0.00193)	-24.2% (-0.02280)	-43.6% (-0.04110)	-45.0% (-0.04243)	

Detection Limits (LoB, LoD, LoQ) - Blood Bank mode

Table 5-7. PLT and RBC Component Sample Detection Limits - rWBC

Parameter	Product mode	LoB	LoD	LoQ	Acceptance Criteria		
					LoB	LoD	LoQ
WBC ($10^3/\mu L$)	PLT	0.0001	0.0004	0.0004	≤ 0.0010	≤ 0.0016	≤ 0.0016
	RBC	0.0001	0.0004	0.0004			

Conclusion:

The proposed Sysmex XN-10 Automated Hematology Analyzer Blood Bank mode and its predicate devices, BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent, have similar 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 devices. 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 residual WBC parameter is equivalent to the predicate devices, BD FACSCalibur Flow Cytometer System with the BD LeucoCOUNT Reagent for residual WBC.