510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K230887

B Applicant

Sysmex America, Inc.

C Proprietary and Established Names

Sysmex XQ-Series (XQ-320) 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:

New device

B Measurand:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#

C Type of Test:

Quantitative complete blood count (CBC) with 3-part leukocyte differential: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The XQ-Series analyzer (XQ-320) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XQ-320 analyzer classifies and enumerates the following parameters in venous and capillary whole blood samples collected in K2 or K3 EDTA anticoagulant: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:
Sysmex XQ-320 analyzer

IV Device/System Characteristics:

A Device Description:

The Sysmex XQ-Series (XQ-320) automated hematology analyzer is a multi-parameter hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XQ-320 analyzer classifies and enumerates whole blood parameters on whole blood samples collected in K_2 or K_3EDTA anticoagulant. The XQ-320 analyzer consists of one principal unit, which aspirates and dispenses diluent to prepare blood dilutions and analyzes whole blood samples. The XQ-320 analyzer uses a built-in monitor to operate the analyzer and process data. The operator mixes the sample manually, then introduces the sample tube to the aspiration pipette with the cap off, and presses the start switch to execute aspiration and analysis.

The XQ-320 automated hematology analyzer consists of two principal analysis modes:
1. Whole Blood Analysis Mode is used for testing K_2EDTA or K_3EDTA whole blood samples.
2. Pre-Dilution Analysis Mode is used for testing of microvolumes of K_2EDTA or K_3EDTA whole blood samples. Venous whole blood containing anticoagulant is directly added to diluent to create a 1:7 dilution (1 part sample and 6 parts diluent).

B Principle of Operation:

The XQ-320 analyzer performs analysis by means of Direct Current (DC) detection method and non-cyanide hemoglobin (HGB) analysis method (colorimetric method). The sample is aspirated, measured, and delivered into a mixing chamber where it is diluted. Then lysing reagent is added to dissolve red cells and release the hemoglobin. The lysed sample is transferred to the transducer, where the volume and number of blood cells are determined by the DC detection

method. Then remaining parameters are calculated by a microprocessor, based upon the measured values.

The leukocyte 3-part differential is determined by size particle distribution. WBC particle size distribution is separated into small white blood cells, medium white blood cells, and large white blood cells by the 3-fractional method.

C Instrument Description Information:

1. Instrument Name:

   Sysmex XQ-Series (XQ-320) Automated Hematology Analyzer

2. Specimen Identification:

   Sample number is manually entered or scanned using a handheld barcode reader.

3. Specimen Sampling and Handling:

   Venous and capillary whole blood samples are collected in K_2 or K_3EDTA anticoagulant. Samples should be analyzed within 4 hours after collection. If the sample is not analyzed within 4 hours, the sample should be stored at 2–8°C for 24 hours. Refrigerated samples should remain at room temperature for at least 15 minutes prior to analysis. Perform gentle inversion prior to analysis.

4. Calibration:

   The SCS-1000 Calibrator (K943268) is used for calibration of the instrument for WBC, RBC, HGB, HCT, and PLT. Calibration is performed as needed (e.g., when QC data is fluctuating) to ensure accuracy of the system.

5. Quality Control:

   There are three levels of quality control material (low, normal, and high; EIGHTCHECK-3WP X-TRA, K852992) to be used to monitor the performance of the XQ-320 analyzer. Quality control should be performed at the appropriate timing according to the operation of the facility.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sysmex XN-Series modules (XN-10, XN-20) Automated Hematology Analyzers

B Predicate 510(k) Number(s):
K112605

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230887	K112605
Device Trade Name	Sysmex XQ-320 Automated Hematology Analyzer	Sysmex XN-Series modules (XN-10, XN-20) Automated Hematology Analyzers
General Device Characteristic Similarities		
Intended Use/Indications For Use	The XQ-Series analyzer (XQ-320) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XQ-320 analyzer classifies and enumerates the following parameters in venous and capillary whole blood samples collected in K2 or K3 EDTA anticoagulant: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, MPV, NEUT%/#, LYMPH%/#, and MXD%/#.	The XN-Series modules (XN-10, XN20) are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, 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 fluid (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 anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, RDW-CV, RDW-SD, MPV,	Same

Device & Predicate Device(s):	K230887	K112605
	NEUT%/#, and LYMPH%/#	
Analysis Modes	Manual Analysis Mode [Whole Blood] mode [Pre-Dilute] mode	Same
Sample Aspiration/Fluidic Pathway	Single Pathway	Same
Measuring Channels	RBC/PLT, HGB	Same
Specimen Type	K_2EDTA/K_3EDTA venous and capillary	Same
General Device Characteristic Differences	K230887	K112605
Specimen Type	Not available	Body Fluids Analysis Mode (CSF, Peritoneal, Pleural, and Synovial Fluids)
Test Principle	DC detection method, non-cyanide hemoglobin analysis method	Flow cytometry method (using a semiconductor laser) and SLS hemoglobin method
Parameters	MXD%/# (MONO+EO+BASO combined)	MONO%/#, EO%/#, and BASO%/# separately
	Not available	IG%/#, RET%/#, IPF, IRF, RET-He PLT (PLT-F), NRBC%/#, WBC BF, RBC-BF, MN%/#, PMN%/#, and TC-BF
Reagents	Not available	FLUOROCELL WNR (Stain) FLUOROCELL WDF (Stain) FLUOROCELL RET (Stain) FLUOROCELL PLT (Stain)
	CELLPACK (Diluent)	CELLPACK DFL (Diluent) CELLPACK DCL (Diluent)
	STROMATOLYSER-WH (Lyse)	SULFOLYSER® (Lyse) LYSERCELL WNR (Lyse) LYSERCELL WDF (Lyse)
	CELLCLEAN (Cleaning solution)	CELLCLEAN AUTO (Cleaning solution)

Device & Predicate Device(s):	K230887	K112605
Measured Channels	Not available	WNR, WPC, WDF, PLT-F, RET
WBC differentials	3-Part	6-Part
Controls	EIGHTCHECK-3WP_X-TRA (3 levels)	XN-Check (3 levels) XN Check BF (2 levels)
Calibrators	SCS-1000	XN CAL, XN CAL PF
Analysis Modes	Sampler Analysis: Mode: Not available Manual Analysis Mode: Not Available	Sampler Analysis: Mode: Sample rack Sampler Manual Analysis Mode: [LWBC] Mode Body Fluid Mode
Throughput	Whole Blood Mode: Approximately 70 samples/hour Pre-Dilution mode: Approximately 60 samples/hour	Whole Blood Mode: 100 samples/hour maximum depending on mode used. Pre-Dilution mode: Approximately 90 samples/hour maximum depending on mode used.
Sample Aspiration Volumes	Whole Blood Mode: 16 µL Pre-Dilution Mode: 65 µL Body Fluid Mode: Not available	Whole Blood Mode: 88 µL Pre-Dilution Mode: 70 µL Body Fluid Mode: 88 µL
Software-based Rules	No rules-based rerun/reflux	Rules-based rerun/reflex

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3 (R2019): Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.
- CLSI H26-A2 Vol. 30 No. 14: Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition.
- CLSI EP07-ED3: Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition.
- CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition.
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.
- CLSI EP06: CLSI. Evaluation of Linearity of Quantitative Measurement Procedures – 2nd Edition.
- CLSI H20-A2: Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition.
- CLSI EP37-Ed1: Supplemental Tables for Interference Testing in Clinical Chemistry – 1st Edition.
- CLSI EP12-Ed3 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Third Edition.

- IEC 61326-2-6 Ed 3.0 2020-10 Electrical equipment for measurement, control and laboratory use - EMC requirements.
- IEC 61010-1:2010+A1Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General req.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Repeatability Study

Repeatability Study

Within-run repeatability studies were performed for all claimed parameters using residual venous whole blood samples collected in K2EDTA anticoagulant. Samples included in the study targeted the low, normal, and upper end of the analytical measuring range of direct measured parameters (WBC, RBC, HGB, HCT, and PLT) and medical decision levels (MDLs) of WBC and PLT parameters. Each sample was tested in one run with ten replicates by the same operator on the same day in the whole blood mode at four U.S. sites (three external clinical sites and one internal site). A total of 11 operators were enrolled across the sites. The mean, standard deviation (SD), and coefficient of variation were calculated for each parameter. All results met the pre-defined acceptance criteria.

Measurand	Sample level	N	Interval	Mean	SD	%CV
WBC (x 10^3/uL)	MDL	30	0.67 – 0.84	0.75	0.04	4.45
	Low	30	1.21 – 1.91	1.64	0.04	2.44
	Normal	30	9.81 – 10.65	10.28	0.15	1.45
	High	30	70.97 – 93.53	83.94	0.61	0.73
RBC (x 10^6/uL)	Low	30	2.03 – 2.85	2.53	0.02	0.99
	Normal	30	4.41 – 4.94	4.70	0.04	0.84
	High	30	6.16 – 6.80	6.43	0.07	1.05
HGB (g/dL)	Low	30	6.1 – 6.9	6.49	0.06	0.92
	Normal	30	13.5 – 15.5	14.36	0.11	0.79
	High	30	17.4 – 19.2	18.05	0.07	0.38
HCT(%)	Low	30	18.2 – 23.0	20.50	0.24	1.16
	Normal	30	40.2 – 44.6	42.10	0.39	0.93
	High	30	52.3 – 58.7	54.99	0.48	0.87
PLT (10^3/µL)	MDL	30	9 – 26	14.33	2.60	17.11
	Low	30	30 – 44	37.10	3.06	8.28
	Normal	30	216 – 311	271.57	6.50	2.46
	High	30	618 – 982	815.30	13.02	1.67
MCV (fL)	Low	30	66.4 – 88.0	77.73	0.26	0.33
	Normal	30	82.2 – 91.1	86.50	0.43	0.50
	High	30	102.9 – 112.6	108.77	0.52	0.47
MCH (pg)	Low	30	20.3 – 25.7	23.50	0.30	1.26
	Normal	30	26.4 – 31.0	28.33	0.29	1.02
	High	30	30.7 – 41.8	35.73	0.54	1.45
MCHC (g/dL)	Low	30	26.2 – 28.9	27.80	0.36	1.31
	Normal	30	28.6 – 32.2	30.87	0.31	1.00

Measurand	Sample level	N	Interval	Mean	SD	%CV
	High	30	32.1 – 36.9	34.50	0.47	1.35
RDW-SD (fL)	Low	30	33.7 – 45.5	38.87	0.64	1.67
	Normal	30	41.1 – 58.2	47.77	0.76	1.60
	High	30	72.6 – 96.0	81.40	1.46	1.80
RDW-CV (%)	Low	30	9.5 – 12.6	11.20	0.58	1.04
	Normal	30	13.1 – 15.5	14.37	0.67	1.17
	High	30	17.2 – 29.9	22.60	0.69	1.13
MPV (fL)	Low	30	8.2 – 8.8	8.53	0.95	1.75
	Normal	30	8.3 – 10.4	9.50	1.10	2.01
	High	30	11.1 – 13.0	11.97	1.40	2.50
NEUT (x 10^3/uL)	Low	30	0.39 – 1.37	0.91	3.99	7.91
	Normal	30	1.21 – 8.70	4.69	1.85	3.56
	High	30	3.36 – 41.53	16.38	1.58	2.85
NEUT (%)	Low	30	21.0 – 57.2	38.40	4.88	7.16
	Normal	30	45.9 – 86.2	61.20	1.91	2.50
	High	30	72.5 – 95.9	84.83	2.47	2.72
LYMPH (x 10^3/uL)	Low	30	0.34 – 0.73	0.49	0.01	4.31
	Normal	30	0.67 – 48.39	16.47	0.40	3.15
	High	30	2.23 – 75.29	26.63	0.33	2.29
LYMPH (%)	Low	30	3.4 – 9.9	5.70	0.37	5.95
	Normal	30	19.8 – 32.9	27.97	0.85	3.10
	High	30	61.0 – 87.6	77.67	0.71	0.99
MXD (x 10^3/uL)	Low	30	0.39 – 1.70	0.81	0.08	10.60
	Normal	30	0.59 – 2.39	1.27	0.15	13.11
	High	30	0.39 – 15.45	5.85	0.27	7.47
MXD (%)	Low	30	2.6 – 14.5	6.87	0.65	10.11
	Normal	30	6.7 – 19.2	11.67	1.60	13.00
	High	30	10.0 – 31.6	22.03	1.55	7.17

Reproducibility

A reproducibility studies was performed at three U.S. clinical sites. The study was performed over five days with three Sysmex XQ-320 Automated Hematology Analyzers (one per site) using a single calibrator and one lot of quality control materials (low, normal, high) by seven operators. Two runs per day and three replicates per run were performed at each site for each control level. The SD and %CV were calculated for within-run, between-run, between-day, between-site, and total imprecision for each control level. All results met pre-defined acceptance criteria.

Measurand	Control level	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC (10^3/µL)	Low	90	3.42	0.000	0.00	0.064	1.87	0.042	1.23	0.000	0.00	0.077	2.24
	Normal	90	7.38	0.000	0.00	0.120	1.60	0.050	0.68	0.056	0.75	0.140	1.89
	High	90	19.3	0.040	0.21	0.190	0.97	0.100	0.54	0.110	0.59	0.250	1.28
RBC (10^6/µL)	Low	90	2.45	0.000	0.00	0.034	1.39	0.014	0.56	0.000	0.00	0.037	1.49
	Normal	90	4.59	0.000	0.00	0.047	1.01	0.023	0.51	0.000	0.00	0.052	1.13
	High	90	5.58	0.000	0.00	0.065	1.16	0.027	0.48	0.000	0.00	0.070	1.25
HGB (g/dL)	Low	90	6.61	0.000	0.00	0.05	0.77	0.06	0.92	0.04	0.71	0.09	1.40
	Normal	90	13.3	0.040	0.33	0.04	0.36	0.05	0.39	0.12	0.90	0.15	1.09
	High	90	17.3	0.000	0.00	0.08	0.49	0.06	0.39	0.11	0.61	0.15	0.88
HCT (%)	Low	90	18.5	0.000	0.00	0.26	1.39	0.09	0.53	0.11	0.62	0.30	1.61
	Normal	90	37.4	0.000	0.00	0.40	1.06	0.14	0.37	0.22	0.59	0.47	1.27

Measurand	Control level	N	Mean	Within-run		Between-run		Between-day		Between-site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
	High	90	48.5	0.190	0.39	0.53	1.10	0.05	0.11	0.24	0.50	0.62	1.28
MCV (fL)	Low	90	75.3	0.000	0.00	0.37	0.49	0.37	0.48	0.36	0.48	0.64	0.84
	Normal	90	81.4	0.000	0.00	0.30	0.37	0.45	0.55	0.41	0.50	0.67	0.83
	High	90	86.9	0.070	0.08	0.33	0.38	0.30	0.34	0.41	0.47	0.61	0.70
MCH (pg)	Low	90	27.0	0.000	0.00	0.43	1.59	0.13	0.48	0.25	0.92	0.51	1.90
	Normal	90	29.0	0.000	0.00	0.29	1.01	0.07	0.27	0.28	0.98	0.42	1.43
	High	90	31.0	0.120	0.40	0.34	1.09	0.00	0.00	0.21	0.67	0.42	1.34
MCHC (g/dL)	Low	90	35.8	0.00	0.00	0.56	1.57	0.33	0.93	0.51	1.43	0.83	2.32
	Normal	90	35.6	0.02	0.08	0.35	1.00	0.23	0.65	0.52	1.46	0.67	1.89
	High	90	35.7	0.25	0.71	4.31	5.48	0.00	0.00	0.42	1.16	0.61	1.70
PLT (x10/μL)	Low	90	78	0.00	0.00	4.31	5.48	1.80	2.29	1.05	1.33	4.79	6.09
	Normal	90	238	0.00	0.00	6.99	2.94	2.68	1.13	2.03	0.85	7.76	3.26
	High	90	560	0.00	0.00	13.80	2.47	8.94	1.60	5.49	0.98	17.30	3.10
RDW-SD (fL)	Low	90	26.1	0.00	0.00	0.52	1.99	0.24	0.93	0.51	1.96	0.77	2.95
	Normal	90	28.3	0.00	0.00	0.47	1.65	0.26	0.91	0.22	0.78	0.58	2.04
	High	90	30.8	0.24	0.78	0.37	1.22	0.12	0.40	0.62	2.00	0.77	2.50
RDW-CV (%)	Low	90	9.41	0.00	0.00	0.26	2.75	0.20	2.11	0.08	0.92	0.34	3.58
	Normal	90	8.77	0.00	0.00	0.18	2.01	0.24	2.77	0.00	0.00	0.30	3.42
	High	90	8.58	0.00	0.00	0.17	2.02	0.20	2.28	0.08	0.94	0.27	3.19
MPV (fL)	Low	90	9.08	0.00	0.00	0.16	1.81	0.11	1.20	0.16	1.78	0.26	2.81
	Normal	90	8.90	0.00	0.00	0.09	1.10	0.01	0.21	0.18	2.07	0.21	2.36
	High	90	8.84	0.00	0.00	0.10	1.15	0.05	0.59	0.18	0.21	0.21	2.39
NEUT (x 10^3/uL)	Low	90	2.40	0.000	0.00	0.075	3.13	0.008	0.32	0.021	0.89	0.078	3.27
	Normal	90	4.20	0..46	1.10	0.100	2.44	0.000	0.00	0.050	1.19	0.120	2.93
	High	90	9.10	0.000	0.00	0.200	2.15	0.000	0.00	0.093	1.02	0.220	2.38
NEUT% (%)	Low	90	70.1	0.00	0.00	1.75	2.50	0.40	0.57	0.37	0.53	1.84	2.62
	Normal	90	57.0	0.24	0.43	1.15	2.01	0.00	0.00	0.21	0.36	1.19	2.09
	High	90	47.3	0.00	0.00	0.90	1.90	0.19	0.41	0.31	0.65	0.97	2.05
LYMPH (x 10^3/uL)	Low	90	0.65	0.009	1.34	0.031	4.83	0.015	2.25	0.000	0.00	0.036	5.49
	Normal	90	2.26	0.000	0.00	0.072	3.19	0.022	0.96	0.000	0.00	0.075	3.33
	High	90	6.96	0.000	0.00	0.130	1.90	0.076	1.10	0.059	0.85	0.160	2.35
LYMPH% (%)	Low	90	19.0	0.00	0.00	0.86	4.54	0.24	1.24	0.00	0.00	0.89	4.70
	Normal	90	30.6	0.00	0.00	0.83	2.70	0.00	0.00	0.30	0.98	0.88	2.87
	High	90	36.1	0.00	0.00	0.55	1.51	0.14	0.40	0.21	0.58	0.60	1.67
MXD (x 10^3/uL)	Low	90	0.37	0.000	0.00	0.060	16.20	0.000	0.00	0.012	3.10	0.061	16.50
	Normal	90	0.91	0.000	0.00	0.079	8.60	0.020	2.16	0.011	1.23	0.082	8.95
	High	90	3.20	0.000	0.00	0.170	5.32	0.000	0.00	0.000	0.00	0.170	5.32
MXD% (%)	Low	90	10.9	0.00	0.00	1.76	16.20	0.00	0.00	0.40	3.69	1.81	16.60
	Normal	90	12.4	0.23	1.84	1.02	8.27	0.00	0.00	0.00	0.00	1.05	8.47
	High	90	16.6	0.00	0.00	0.89	5.35	0.00	0.00	0.03	0.18	0.89	5.35

2. Linearity:
   Linearity testing by serial dilution was conducted at one internal site using three Sysmex XQ-320 Automated Hematology Analyzers. A single calibrator lot, control material (WRP CHECK; K960557) and system diluent (CELLPACK) were used to create serial dilutions of sample concentration which spanned the target measurement range of all direct measured parameters (WBC, RBC, HGB, HCT and PLT). Each sample dilutions were measured in replicates of three. All results met predefined acceptance criteria.

Parameter	Linear Range
WBC ($x10^3/\mu L$)	0.20–99.90
RBC ($x10^6/\mu L$)	0.01–7.00
HGB (g/dL)	0.1–25.0
HCT (%)	0.2–60.0
PLT($x10^3/\mu L$)	5–999

3. Analytical Specificity/Interference:
Interfering substances studies were conducted for Bilirubin F, Bilirubin C, Chyle, Hemolytic Hemoglobin, Lipids, and high WBC, RBC, and platelet counts to determine the concentration that impact all claimed parameters on the Sysmex XQ-320 Automated Hematology analyzer. Whole blood K_2EDTA samples were collected from donors for this study and varying concentrations of interferent was added to obtain concentrations. The tubes were mixed, and measurements were repeated in four consecutive batches on the XQ-320 automated hematology analyzer. The following table includes the results of the study:

Interferent	Conclusion
Bilirubin F	There was no significant Bilirubin F interference up to a concentration of 40.0 mg/dL for all parameters.
Bilirubin C	There was no significant Bilirubin C interference up to a concentration of 40 mg/dL for all parameters.
Chyle	There was no significant Chyle interference up to a concentration of 2,880 FTU (Formazine Turbidity Unit) for WBC, up to a concentration of 1,440 FTU for NEUT%, LYMPH%, and MXD% and up to a concentration of 720 FTU for LYMPH#. There was no significant Chyle interference up to a concentration of 3,600 FTU for the other parameters. Significant Chyle interference was observed for MXD# at a concentration of 720 FTU.
Hemolytic Hemoglobin	There was no significant Hemolysis interference up to a concentration of 800 mg/dL for HGB and 400 mg/dL for MCHC. For the other parameters, no significant interference was observed up to a concentration of 1,000 mg/dL.
Lipids	There was no significant Lipid interference up to a concentration of 0.20 g/dL for HGB, MCH, and MCHC. There was no significant Lipid interference up to a concentration of 1.00 g/dL for MPV. There was no significant Lipid interference up to a concentration of 2.00 g/dL for the other parameters.
High white blood cell counts	There was no significant WBC interference up to a concentration of 93.53 x 10^3 cells/µL for RBC, HGB, HCT and MCV. There was no significant WBC interference up to a concentration of 72.08 x 10^3 cells/µL for PLT.
High red blood cell counts	There was no interference from high RBCs at the upper measuring range in measuring WBC, RBC, HGB, and PLT.

	There was no significant RBC interference up to a concentration of 6.64 x 10^6 cells/µL for HCT.
High platelet counts	There was no significant PLT interference up to a concentration of 955 x 10^3 cells/µL for WBC, RBC, HGB, HCT, PLT, and MPV.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Sample Stability:
The evaluation of whole blood sample stability was conducted at one site using twenty (10 normal and 10 abnormal) residual K_2EDTA whole blood samples. Samples were split into two sets stored at room temperature (18–26°C) and refrigerated temperature (2–8°C). Room temperature samples were tested in duplicate at baseline (T0), 4, 8, 12, and 13 hours and refrigerated samples were tested at baseline T0, 8, 12, 24, and 25 hours in singlet. The mean, standard deviation, mean difference and percent difference from the baseline mean of each sample result were calculated for each parameter at each time interval for both conditions. All results were within the established acceptance criteria. The data support a whole blood sample stability of 12 hours at room temperature (18–26°C) and 24 hours at refrigerated temperature (2–8°C).

5. Detection Limit:

Limits of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) were determined for the direct measured WBC, RBC, HGB, HCT and PLT parameters on the Sysmex XQ-320 Automated Hematology Analyzer.

In LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurement results per parameter. To determine the LoD and LoQ, four low concentration samples were analyzed on the Sysmex XN-10 automated hematology analyzer (K112605) to assign the reference value. The low-level samples were then measured in replicates of five over a period of three days using two reagent lots, to yield 120 total measurement results per parameter.

The results of the LoB, LoD, and LoQ are provided in the table below.

Parameter	**LoB**	**LoD**	**LoQ**
WBC (x10^6/µL)	0.00	0.03	0.17
RBC (x10^6/µL	0.00	0.01	0.01
HGB (g/dL)	0.00	0.1	0.1
HCT (%)	0.00	0.1	0.1
PLT (x10^3/µL)	0	1	2

6. Assay Cut-Off:

Not applicable.

7. Carry-Over:

Carryover on the Sysmex XQ-320 Automated Hematology analyzer was evaluated by assaying venous whole blood collected in K_2EDTA with high WBC, RBC, HGB, HCT, and PLT counts three consecutive times followed immediately by testing samples with low target values around medical decision levels three consecutive times. Three sets of carryover sequences were run for each measurand in the whole blood mode at three clinical sites. The results of the carryover study demonstrated the Sysmex XQ-320 Automated Hematology Analyzer is not impacted by carryover.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was conducted to assess the performance of the Sysmex XQ-320 Automated Hematology analyzer compared to the predicate device, Sysmex XN-10 (K112605). A total of 628 (611 native and 17 contrived) residual and prospectively collected venous whole blood samples in K2EDTA anticoagulant from pediatrics (<21 years) and adult (≥21 years) subjects including a variety of disease states (e.g., chronic leukemia (lymphocytic), pathological WBCs, hepatocellular carcinoma, bacterial infection, acute encephalopathy etc.) were enrolled in the study. Sample demographics from all sites included 172 pediatric subjects and 433 adults and 23 subjects with age not reported. Of this total, 43.8% were male, 52.2% female and 4.0% with sex not reported. The results of the regression analyses including 95% confidence interval (CI) for the slope, intercept and correlation coefficient were computed for each parameter using the Deming method with results from the Sysmex XQ-320 Automated Hematology Analyzer against the results from the Sysmex XN-10 analyzer. All results were within predefined acceptance criteria.

Measurand (unit)	N	Result Range	Correlation Coefficient	Slope (95%CI)	Intercept 95% CI
WBC (x 10^3/µL)	378	(0.31–98.67)	0.9994	0.992 (0.988, 0.996)	0.215 (0.144, 0.285)
RBC (x 10^6/µL)	385	(1.10–6.78)	0.9984	0.970 (0.965, 0.976)	0.107 (0.083, 0.130)
HGB (g/dL)	385	(3.2–23.8)	0.9987	0.974 (0.969, 0.979)	0.45 (0.39, 0.52)
HCT (%)	379	(11.1–59.1)	0.9965	0.964 (0.956, 0.972)	0.62 (0.30, 0.93)
MCV (fL)	385	(52.5–131.6)	0.9881	1.005 (0.990, 1.021)	-1.98 (-3.43, -0.53)
MCH (pg)	385	(13.1– 40.9)	0.9861	0.997 (0.981, 1.014)	0.57 (0.08, 1.06)
MCHC (g/dL)	385	(22.4–40.2)	0.8914	0.880 (0.839, 0.922)	4.83 (3.52, 6.13)
PLT (x 10^3/uL)	382	(6–941)	0.9960	0.989 (0.980, 0.998)	-1.9 (-4.9, 1.0)
RDW-SD (fL)	384	(33.6–105.5)	0.9467	1.028 (0.995, 1.062)	-5.03 (-6.83, -3.23)
RDW-CV (%)	385	(11.2–26.5)	0.9645	1.167 (1.136, 1.198)	-3.15 (-3.65, -2.65)
MPV (fL)	359	(8.2–14.5)	0.9027	0.912 (0.870, 0.954)	0.40 (-0.05, 0.86)

Measurand (unit)	N	Result Range	Correlation Coefficient	Slope (95%CI)	Intercept 95% CI
NEUT# (x 10^3/uL)	262	(0.36–57.75)	0.9959	1.020 (1.009, 1.031)	-0.176 (-0.299, -0.052)
LYMPH# (x 10^3/uL)	363	(0.10–99.84)	0.9962	1.012 (1.003, 1.021)	0.109 (-0.005, 0.222)
MXD# (x 10^3/uL)	262	(0.02–3.00)	0.8525	1.280 (1.197, 1.364)	-0.247 (-0.394, -0.101)
NEUT (%)	262	(15.9–96.7)	0.9600	1.017 (0.981, 1.052)	-2.32 (-4.58, -0.06)
LYMPH (%)	364	(0.5–95.2)	0.9827	1.031 (1.011, 1.051)	0.18 (-0.56, 0.91)
MXD (%)	262	(1.0–18.0)	0.5933	1.415 (1.268, 1.562)	-4.25 (-6.06, -2.44)

2. Matrix Studies

Anticoagulant Comparison Study (K_2EDTA versus K_3EDTA) – Whole Blood

Anticoagulant comparison study was performed to evaluate comparability between K_2EDTA versus K_3EDTA anticoagulated whole blood samples on the Sysmex XQ-320 Automated Hematology analyzer. A total of 53 paired whole blood samples (K_2EDTA versus K_3EDTA) were collected from adult (>21 years) donors. The samples were run in singlet within 8 hours of collection in the whole blood mode. The results from the K_2EDTA whole blood samples were compared to the corresponding results of the K_3EDTA sample for the same donor. The results of the regression analysis and bias estimates between K_2EDTA versus K_3EDTA anticoagulated whole blood samples met the acceptance criteria for all applicable parameters and suggest there is no difference in performance between K_2EDTA and K_3EDTA whole blood samples.

Comparison of Venous Whole Blood versus Capillary Whole Blood

A study was performed to evaluate comparability between venous whole blood and capillary whole blood samples on the Sysmex XQ-320 Automated Hematology analyzer. A total of 42 paired venous whole blood and capillary whole blood samples (K_2EDTA) were drawn from adult (>21 years) donors for this study. The venous whole blood sample results were compared to the corresponding results of the capillary sample for the same donor. The results of the regression analysis and bias estimates met the acceptance criteria for all applicable parameters and suggest there is no difference in performance between venous whole blood and capillary whole blood samples.

Whole Blood K_2EDTA Normal Tube versus Micro-collection tube

A comparison study of K_2EDTA tubes and micro-collection tubes without anticoagulant were performed to determine the presence or absence of matrix effect between the sample tubes on the Sysmex XQ-320 Automated Hematology analyzer. A total of 183 residual K_2EDTA (4 mL tubes) whole blood samples with analyte concentrations spanning the analytical measuring range were run in singlet in the whole blood mode. Within two hours of analysis of the 4 mL K_2EDTA tubes, the samples were remixed, then transferred to micro collection tubes (without anticoagulant additive), then analyzed in singlet in the whole blood mode. The results from the K_2EDTA whole blood samples were compared to the corresponding results of the micro-collection sample tube for the same patient sample. The

results of the regression analysis and bias estimates met the acceptance criteria for all applicable parameters and suggest there is no matrix effect between samples tubes on the Sysmex XQ-320 Automated Hematology Analyzer.

Whole Blood K_2EDTA mode versus Predilute mode

A total of 35 residual K_2EDTA (4 mL tubes) anticoagulated whole blood samples were evaluated to determine comparability between the whole blood and predilute mode on Sysmex XQ-320 Automated Hematology analyzer. Following the analysis of the whole blood samples, a 1:7 predilute sample was prepared for each whole blood sample by adding 120 µL of system diluent (CELLPACK) and 20 µL of whole blood into plain micro-collection tubes. The prediluted samples were thoroughly mixed by gentle inversion and run in the predilute mode of the Sysmex XQ-320 Automated Hematology Analyzer with caps off. The results from the predilute mode are automatically multiplied by 7 before results are displayed, therefore no additional calculation is required. The results from the K_2EDTA whole blood samples were compared to the corresponding results of the prediluted sample for the same patient sample. The results of the regression analysis and bias estimates met the acceptance criteria for all applicable parameters.

C Clinical Studies:

1. Clinical Sensitivity:

Sensitivity/specificity studies were conducted to evaluate the flagging capabilities of the Sysmex XQ-320 Automated Hematology analyzer using patient samples representing a variety of abnormal conditions in comparison to manual differential counts and peripheral blood smear review by experienced examiners using light microscopy (reference method) at each of the three external clinical sites and one internal site from the method comparison study. Three blood film slides were prepared for each sample for manual measurement. The flagging results from the Sysmex XQ-320 Automated Hematology Analyzers for normal (no flags) and abnormal (flags present) were compared to manual differential counts and peripheral blood smear review using light microscopy. A 2x2 table was constructed to determine sensitivity and specificity for both distributional and morphological abnormalities. The sample size (N), number of true positives (TP), false positives (FP), true negative (TN), false negatives (FN), sensitivity, specificity, and overall percent agreement are presented in the following table.

Distributional and Morphological Abnormal Flagging Summary – All Sites Combined

Abnormal Flag	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)	Overall % Agreement
Distributional Flag	437	202	32	181	22	90.2% (85.6%, 93.4%)	85.0% (79.6%, 89.2%)	87.6% (84.2%, 90.4%)
Morphological Flag	542	131	55	287	69	65.5% (58.7%, 71.7%)	83.9% (79.7%, 87.4%)	77.1% (73.4%, 80.5%)
Distributional and/or Morphological Flag	560	300	58	164	38	88.8% (84.9%, 91.7%)	73.9% (67.7%, 79.2%)	82.9% (79.5%, 85.8%)

2. Clinical Specificity:

   See sensitivity above.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Expected Values/Reference Range:

Verification of Adult Reference Intervals

Verification of adult reference intervals was conducted on the Sysmex XQ-320 Automated Hematology analyzer to demonstrate comparability of whole blood reference intervals for an adult male and female population (>21 years) to ranges established for the Sysmex pocH-100i (K032677). Ninety-nine samples (56 females and 43 males) were tested and compared to pre-established reference intervals to determine if the ranges were applicable for use with the Sysmex XQ-320 Automated Hematology analyzer. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the adult male and female and were determined to be acceptable.

Verification of Pediatric Reference Intervals

Using Pediatric Reference Interval literature source (Wong, E., Brugnara, C., Straseski, J., Kellogg, M., & Adeli, K. 2021. Pediatric Reference Intervals. 8th ed., Hematology Tests (pp. 209-267), Academic Press.), reference interval verification study was performed for the pediatric population. A total of 226 pediatric samples including each subpopulation: 34 neonates (birth–1 month); 63 infants (>1 month–2 years); 63 children (>2 years–12 years); and 66 adolescents (>12 years–21 years) were used in the study. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the pediatric datasets and were determined to be acceptable.

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.