510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k120742

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed parameters: RBC(10^6/μL), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT(10^3/μL), PLT-F(10^3/μL), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC(10^3/μL), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#(10^3/μL), LYMPH#(10^3/μL), MONO# (10^3/μL), EO#(10^3/μL), BASO#(10^3/μL), IG#(10^3/μL), IPF(%), RET#(10^6/μL), RET%, IRF%, RET-HE(pg), NRBC#(10^3/μL), and NRBC% (/100 WBC).

D. Type of Test:

Quantitative

E. Applicant:

Streck

F. Proprietary and Established Names:

XN-CHECK™

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   JPK, mixture, hematology quality control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   XN CHECK is used for control and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers.

   Assayed parameters include: RBC(10^6/µL), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT(10^3/µL), PLT-F(10^3/µL), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC(10^3/µL), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#(10^3/µL), LYMPH#(10^3/µL), MONO# (10^3/µL), EO#(10^3/µL), BASO#(10^3/µL), IG#(10^3/µL), IPF(%), RET#(10^6/µL), RET%, IRF%, RET-HE(pg), NRBC#(10^3/µL), and NRBC% (/100 WBC).

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Sysmex XN (XN-10, XN-20) analyzers

I. Device Description:

XN CHECK™ is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s) and stabilized nucleated red blood cell component(s) in a preservative medium. The control includes three levels (i.e. low, medium and high) which are packaged separately in polypropylene plastic vials with screw caps containing 3mL. The vials will be packaged in (4) welled vacuum formed clamshell container with the Instructions for Use (IFU) / assay sheet. The product must be stored at 2 - 8°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Streck e-CHECK (XE) ®

2. Predicate 510(k) number(s):

   k063218

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	XN CHECK is used for control and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include: RBC(10^6/μL), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT(10^3/μL), PLT-F(10^3/μL), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC(10^3/μL), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#(10^3/μL), LYMPH#(10^3/μL), MONO#(10^3/μL), EO#(10^3/μL), BASO#(10^3/μL), IG#(10^3/μL), IPF(%), RET#(10^6/μL), RET%, IRF%, RET-HE(pg), NRBC#(10^3/μL), and NRBC% (/100 WBC)	e-CHECK (XE)® is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte, and nucleated red blood cell (NRBC) parameters on Sysmex XE-Series instruments.
Control levels	3 levels	Same
Open-vial stability	7 days	Same
Closed-vial stability	84 days	Same
Storage conditions	2 - 8°C	Same

Differences		
Item	Device	Predicate
Reagents	XN CHECK contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s), and stabilized nucleated red blood cell component(s) in a preservative medium.	The e-CHECK(XE) control consists of stabilized human and animal blood. This product is provided in three levels that vary in concentration by parameters. Vials are labeled L1, L2, and L3

K. Standard/Guidance Document Referenced (if applicable):

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, October 2010

CLSI EP5-A2 Methods, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

L. Test Principle:

Tri-level XN CHECK™ was designed to evaluate the accuracy and precision of the Sysmex XN Series instruments. XN CHECK™ is for in-vitro diagnostic use only by laboratory professionals.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Data were collected internally and at two external sites across 4 different Sysmex XN-10 and XN-20 analyzers, throughout the product dating claim with 3 separately manufactured lots of XN-CHECK™. Studies were conducted for each lot at all three (3) sites, including a U.S site. The external sites performed 10 consecutive runs on each XN Series Instrument with separate vials of control from each lot. Control materials were shipped, stored, mixed, and handled in accordance with the instruction for use. Acceptance criteria were based on compilation of the CV% for each measurand. Results collected across the three separately manufactured lots of XN CHECK™ demonstrated consistent recovery across multiple instruments, at multiple sites and were within the parameter specific assay assignment ranges set forth for each measurand (shown in the tables below).

Level 1											
Measurand (%CV)											
	WBC	**RBC**	**HGB**	**HCT**	**MCV**	**MCH**	**MCHC**	**PLT**	**PLT-F**	**RDW-SD**	**RDW-CV**
Lot 1185	2.70	1.04	1.26	1.16	1.15	1.55	1.60	15.50	6.93	1.36	1.07
Lot 1241	2.51	1.22	1.25	1.79	1.24	1.44	1.78	22.46	11.54	1.17	0.74
Lot 1297	2.36	1.07	1.16	2.22	1.74	1.25	1.77	11.13	3.72	1.29	1.27
CV% Acceptance Criteria	5	5	5	5	5	5	5	25	15	5	5

Level 2											
Measurand (%CV)											
	WBC	**RBC**	**HGB**	**HCT**	**MCV**	**MCH**	**MCHC**	**PLT**	**PLT-F**	**RDW-SD**	**RDW-CV**
Lot 1185	1.92	0.94	1.11	1.75	1.48	1.39	2.14	2.34	7.71	2.21	0.56
Lot 1241	1.97	1.03	0.91	2.07	1.38	1.35	2.28	3.68	9.73	2.06	1.00
Lot 1297	1.80	1.13	0.77	2.11	1.58	1.56	2.43	3.00	5.64	2.16	0.89
CV% Acceptance Criteria	5	5	5	5	5	5	5	5	10	5	5

Level 3											
Measurand (%CV)											
	WBC	**RBC**	**HGB**	**HCT**	**MCV**	**MCH**	**MCHC**	**PLT**	**PLT-F**	**RDW-SD**	**RDW-CV**
Lot 1185	1.40	0.88	1.44	1.97	1.57	1.36	2.21	2.06	3.24	2.42	0.82
Lot 1241	1.24	1.07	1.01	2.28	1.46	1.33	2.36	2.76	3.29	1.72	0.64
Lot 1297	1.48	0.84	1.02	1.81	1.58	1.42	2.11	2.71	2.91	1.97	0.83
CV% Acceptance Criteria	5	5	5	5	5	5	5	5	5	5	5

Level 1										
Measurand (%CV)										
	MPV	**NEUT#**	**LYMP#**	**MONO#**	**EO#**	**BASO#**	**IG#**	**NEUT%**	**LYMP%**	**MONO%**
Lot 1185	5.20	3.93	6.25	8.56	8.03	5.30	11.86	2.89	4.97	8.73
Lot 1241	5.50	3.61	6.17	11.81	7.14	4.76	4.65	2.66	5.42	11.77
Lot 1297	4.39	4.02	6.41	10.26	8.13	4.87	4.70	2.66	5.38	11.13
CV% Acceptance Criteria	10	10	10	20	15	10	15	5	10	20

Level 2										
Measurand (%CV)										
	MPV	**NEUT#**	**LYMP#**	**MONO#**	**EO#**	**BASO#**	**IG#**	**NEUT%**	**LYMP%**	**MONO%**
Lot 1185	2.33	3.08	5.08	8.71	7.41	3.48	3.19	2.35	4.57	8.67
Lot 1241	1.63	2.78	4.78	8.27	6.82	3.28	3.40	1.92	4.14	8.18
Lot 1297	1.46	2.59	4.76	8.60	8.23	2.94	3.33	2.01	4.21	8.67
CV% Acceptance Criteria	5	10	10	15	15	5	5	5	10	15

Level 3										
Measurand (%CV)										
	MPV	**NEUT#**	**LYMP#**	**MONO#**	**EO#**	**BASO#**	**IG#**	**NEUT%**	**LYMP%**	**MONO%**
Lot 1185	1.51	2.83	4.39	7.22	7.88	2.94	3.49	2.38	3.98	7.18
Lot 1241	1.01	1.94	3.74	7.30	7.27	2.77	3.42	1.55	3.06	7.75
Lot 1297	1.24	2.57	4.01	6.28	6.68	2.77	3.64	1.89	3.52	6.45
CV% Acceptance Criteria	5	5	10	15	15	5	5	5	5	15

Level 1										
Measurand (%CV)										
	EO%	**BASO%**	**IG%**	**NRBC#**	**NRBC%**	**RET#**	**RET%**	**IRF**	**RET-He**	**IPF**
Lot 1185	7.99	4.35	11.57	14.61	14.76	4.76	4.26	21.77	2.41	2.67
Lot 1241	6.63	3.79	3.63	15.74	15.89	5.04	4.51	31.71	3.20	2.65
Lot 1297	7.63	3.74	3.69	10.00	9.98	9.34	9.19	15.65	2.78	2.37
CV% Acceptance Criteria	15	10	15	N/A	20	15	15	N/A	5	5

Level 2										
Measurand (%CV)										
	EO%	**BASO%**	**IG%**	**NRBC#**	**NRBC%**	**RET#**	**RET%**	**IRF**	**RET-He**	**IPF**
Lot 1185	7.24	2.71	3.04	5.30	5.27	4.72	4.66	17.07	2.39	2.72
Lot 1241	6.70	2.59	3.07	6.07	6.22	3.98	3.99	24.15	3.12	12.59
Lot 1297	7.94	2.34	2.46	5.07	5.24	9.41	9.59	14.41	2.85	3.56
CV% Acceptance Criteria	15	5	5	10	10	15	15	N/A	5	15

Level 3										
Measurand (%CV)										
	EO%	**BASO%**	**IG%**	**NRBC#**	**NRBC%**	**RET#**	**RET%**	**IRF**	**RET-He**	**IPF**
Lot 1185	7.99	2.48	3.17	3.62	3.80	7.68	7.94	18.91	3.89	2.92
Lot 1241	7.04	2.52	2.97	3.17	3.19	5.28	5.51	23.03	3.96	3.95
Lot 1297	6.66	2.23	3.18	3.39	3.43	9.51	9.62	13.10	3.23	3.55
CV% Acceptance Criteria	15	5	10	10	10	15	15	N/A	5	10

b. Linearity/assay reportable range:

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignments:
Value assignment was performed on four Sysmex (XN-10 and XN-20) analyzers using two vials of each control level tested a minimum of five times per vial. Data were entered into the internally validated QC link database program (validation number PQ-062) to calculate the mean, standard deviation (SD), and coefficient of variation (CV) for each parameter analyzed. The database allows computation and comparison of data that is used in the assay value assignment process as defined by controlled documents. The expected range values assigned to the measurands were based on the ± 3.0 SD of the total-run data and established product performance characteristics. Total-run encompasses the values generated over multiple combined data sets compiled for all three lots of control.

Reagent Stability
Acceptance criteria for open and closed-vial stability was based on a compilation of the CV% for each measurand over data collected across four different Sysmex XN-10 and XN-20 analyzers, at 3 sites, throughout the product dating claim, with three separately manufactured lots of XN CHECK™.

Open-vial stability: A 7 day open-vial stability claim was validated at the end of the 84-day product expiration claim. Two vials of control/level from each of the three reference lots were analyzed on XN series (XN-10, XN-20) analyzer in duplicate over a period of eight days. On a daily basis, vials were removed from storage and mixed in accordance with the instructions for use to simulate daily customer usage/handling.

Closed-vial stability: Three separately manufactured lots of XN CHECK™ lots were set up to validate closed-vial stability performance throughout the 84 days expiration dating at refrigerated temperatures (2-8^{o}C). Data were collected using CLSI EP5-A2 methods on XN series (XN-10, XN-20) analyzer.

All reported CV% values for open and closed vial reagent stability were within the acceptable threshold values as shown in the tables above in section M. 1(a).

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The end-user is instructed to refer to the product assay sheet accompanying the instructions for use.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.