510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k120747

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed hematology parameter: PLT-F (10^3/µL)

D. Type of Test:

Quantitative

E. Applicant:

Streck

F. Proprietary and Established Names:

XN-Cal™ PF

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8150 - Calibrator for cell indices

2. Classification:

   Class II

3. Product code:

   KRX – Calibrator for cell indices

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   XN CAL PF is used for calibration and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. Assayed parameter is: PLT-F ($10^3/\mu L$).

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 CAL™ PF is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s), stabilized platelet component(s) in a preservative medium. The single level calibrator is packaged in polypropylene plastic vials with screw caps. The vials will be packaged in (5) welled or (1) 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):

   X-CAL™ manufactured by Streck

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

   k083200

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	XN CAL PF is used for calibration and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. The assayed parameter is: PLT-F ($10^3/\mu L$).	X-CAL is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.
Closed-vial stability	35 days	Same

Similarities		
Item	Device	Predicate
Storage conditions	2 - 8°C	Same

Differences		
Item	Device	Predicate
Reagents	XN CAL PF contains the following: stabilized red blood cell component(s), and stabilized platelet component(s), in a preservative medium.	X-CAL is composed of a mixture of stabilized human and animal blood cells. The cells are suspended in a solution containing biological salts and anti-microbial preservatives
Open-vial stability	4 hours	24 hours

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:

XN CAL™ PF is designed to function as a substitute for fresh whole blood to calibrate the Sysmex XN Series instruments. .XN CAL™ PF is used to calibrate the platelet count obtained for the PLT-F channel of the Sysmex XN Series analyzers.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Data was collected internally and at two external sites across 4 different Sysmex XN-10 and XN-20 analyzers with 3 separately manufactured lots of XN-CAL™ PF. Studies were conducted for each lot at all three (3) sites. The external sites performed 10 consecutive runs on each XN Series Instrument with separate vials of calibrator from each lot. Control materials were shipped, stored, mixed, and handled in accordance with the instructions for use. The acceptance criteria were based on a compilation of the CV% for PLT-F. Results collected across the three separately manufactured lots of XN CAL™ PF demonstrate consistent recovery across multiple instruments, at multiple sites within the parameter specific assay assignment range set forth for PLT-F as shown in the table below.

XN CAL PF CV% summary

Lot #	PLT-F (%CV)
1290	1.86
1318	2.59
1346	2.05
Maximum CV% Acceptance Criteria	5

b. Linearity/assay reportable range:

Not applicable

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

Value assignment:
Streck performed analyses on four Sysmex (XN-10 and XN-20) analyzers using two vials of calibrator 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. Final assigned values were determined using data collected and established product performance characteristics. Expected range values assigned to the calibrator were based on ± 2.5 SD calculated from the total-run data.

Reagent Stability
The acceptance criterion for open and closed-vial stability was based on a compilation of the CV% for PLT-F over data collected across four different Sysmex XN-10 and XN-20 analyzers, at three sites, throughout the product dating claim, with three separately manufactured lots of XN CAL™ PF.

Open-vial stability: A 4 hour open-vial stability claim was validated at the end of the 35-day product expiration claim on XN series (XN-10, XN-20) analyzer. Two vials of calibrator from each reference lot were analyzed in duplicate for three consecutive days (n=12).

Closed-vial stability: Three separately manufactured lots of XN CAL™ PF were set up to validate closed-vial stability performance throughout the 35-day expiration dating at refrigerated temperatures (2 - 8^{o}C) on XN series (XN-10, XN-20) analyzer. Data were collected according to CLSI EP5-A2 methods.

CV% value for open and closed vial XN CAL™ PF stability was within the acceptable threshold value as shown in the table 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 product 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.