510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DEcision SUMMARY

A. 510(k) Number:

k120745

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed hematology parameters: WBC (10^3/μL), RBC (10^6/μL), HGB (g/dL), HCT (%), PLT (10^3/μL), and RET (%)

D. Type of Test:

Quantitative

E. Applicant:

Streck

F. Proprietary and Established Names:

XN-Cal™

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 is used for the calibration and calibration verification of Sysmex XN series analyzers (XN-10, XN-20) analyzers. Assayed parameters include: WBC (10^3/μL), RBC (10^6/μL), HGB (g/dL), HCT (%), PLT (10^3/μL), and RET (%).

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 Series (XN-10, XN-20) analyzers

I. Device Description:

XN CAL™ 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 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™

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

k083200

3. Comparison with predicate:
### Similarities

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>XN CAL is used for the calibration and calibration verification of Sysmex XN series analyzers (XN-10, XN-20) analyzers. Assayed parameters include: WBC (10^3/μL), RBC (10^6/μL), HGB (g/dL), HCT (%), PLT (10^3/μL), and RET (%).</td>
<td>X-CAL is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.</td>
</tr>
<tr>
<td>Closed-vial stability</td>
<td>35 days</td>
<td>Same</td>
</tr>
<tr>
<td>Storage conditions</td>
<td>2 - 8°C</td>
<td>Same</td>
</tr>
</tbody>
</table>

### Differences

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurand</td>
<td>RET%</td>
<td>Not available</td>
</tr>
<tr>
<td>Reagents</td>
<td>XN CAL 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.</td>
<td>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.</td>
</tr>
<tr>
<td>Open-vial stability</td>
<td>4 hours</td>
<td>24 hours</td>
</tr>
</tbody>
</table>

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

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


**L. Test Principle:**

XN CAL™ was designed to function as a substitute for fresh whole blood to calibrate the Sysmex XN Series instruments. This product is for *in-vitro* diagnostic use to calibrate the following parameters: RBC (10^6/μL), HGB (g/dL), HCT (%), PLT (10^3/μL), WBC (10^3/μL), and RET (%).

**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 with 3 separately manufactured lots of
XN-CAL™. 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 each measurand. Results across the three separately manufactured lots of XN CAL™ demonstrated consistent recovery across multiple instruments, at multiple sites within the parameter specific assay assignment ranges set forth for each measurand (see table below).

<table>
<thead>
<tr>
<th>Lot</th>
<th>Measurand (% CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WBC</td>
</tr>
<tr>
<td>1290</td>
<td>2.24</td>
</tr>
<tr>
<td>1318</td>
<td>1.96</td>
</tr>
<tr>
<td>1346</td>
<td>1.92</td>
</tr>
<tr>
<td>Max</td>
<td>CV%</td>
</tr>
</tbody>
</table>

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 value assignment process as defined by controlled documents. Final assignment values were determined using data collected and established product performance characteristics. Expected range values assigned to the measurands were based on 2.5 SD from the total-run data collected for XN CAL™.

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

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) on one analyzer.
Closed-vial stability: Three separately manufactured lots of XN CAL™ were set up to validate closed-vial stability performance throughout the 35-day expiration dating at refrigerated temperatures (2 - 8°C) on XN series (XN-10, XN-20) analyzer. Data were collected using CLSI EP25-A methods.

All CV% values for reagent stability were within the acceptable threshold values 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.