

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

K083200

**B. Purpose for Submission:**

New Device

**C. Measurand:**

White Blood Cells (WBC-C) Count, White Blood Cells Differential(WBC-D), Red Blood Cells (RBC), Nucleated Red Blood Cells (NRBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelets (Plt)

**D. Type of Test:**

Quantitative

**E. Applicant:**

Streck, Inc.

**F. Proprietary and Established Names:**

X-Cal™

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.8150

2. Classification:

Class II

3. Product code:

KRX

4. Panel:

81 (Hematology)

**H. Intended Use:**

1. Intended use(s):

X-Cal™ is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.

2. Indication(s) for use:

X-Cal™ is used to calibrate and verify calibration of Sysmex hematology analyzers. Refer to product assay sheet.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

For use on the Sysmex hematology analyzers.

**I. Device Description:**

X-Cal™ is a stabilized suspension of human and animal blood, in a solution containing biological salts and anti-microbial preservatives. The product is packaged in plastic vials containing 4.6 ml. The closures are polypropylene screw caps with polyethylene liners. The vials are packaged in a five (5) welled vacuum formed “clam-shell” container and must be stored at 2-8° C.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Cal-Chex

2. Predicate K number(s):

K840261

3. Comparison with predicate:

| <b>Similarities</b> |                                                |                 |
|---------------------|------------------------------------------------|-----------------|
| <i>Item</i>         | <i>X-Cal™</i>                                  | <i>Cal-Chex</i> |
| Intended use        | Used to calibrate Sysmex hematology analyzers. | Same            |
| Parameters          | WBC, RBC, nRBC, Hgb, Hct, Plt                  | Same            |
| Reagents            | Stabilized Human and Animal Blood              | Same            |

| <b>Differences</b>    |               |                 |
|-----------------------|---------------|-----------------|
| <i>Item</i>           | <i>X-Cal™</i> | <i>Cal-Chex</i> |
| Open vial stability   | 24 hours      | 5 days          |
| Closed vial stability | 34 days       | 45 days         |
| Storage temperature   | 2 – 8° C      | 2 – 10° C       |

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

H38-P, Calibration and Quality Control of Automated Hematology Analyzers, April 1999, CLSI

**L. Test Principle:**

X-Cal™ is a calibrator assigned model-specific assay target values for primary hematology parameters that are traceable to reference methods. The product is for calibration or calibration verification of the Open/Manual sampling mode of the Sysmex® analyzers listed on the Assay Sheet. Changes made in the Open mode calibration will be proportionally reflected in Closed and Capillary mode values. X-Cal™ is for in-vitro diagnostic use only by laboratory professionals or appropriately trained personnel.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility studies were performed on three different Sysmex® analyzers (XS-1000, XE-2100, XT-2000) using three lots of one level of X-Cal™. Each value was calculated from 10 consecutive analyses performed on a single vial.

A whole blood study on three lots of X-Cal™ was performed by analyzing two whole blood samples 10 times each on the Sysmex XS-1000, XE-2100 and XT-2000 analyzers.

*b. Linearity/assay reportable range:*

Not applicable.

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

**Value assignment:** X-Cal™ values are assigned based on instrument specific requirements. Replicate analyses on multiple vials are performed on the analyzer application (Sysmex analyzers). Assay analysis is performed using two vials, testing each vial a minimum of five times. This ten-run reproducibility event is analyzed to assure that the mean values and CV% meet instrument specific requirements. Sysmex® performs similar analyses using multiple vials and replicate runs, and enters all the data into a database program which confirms that the data supplied by each laboratory meets system requirements. Final assay assignment values are determined using data collection, parity comparison and established product performance characteristics.

**Open vial stability:** The three lots were set up to verify performance throughout a 6 day vial dating, but only claims a 24 hour open vial dating. Each lot was run on the three hematology analyzers on specified days during the six day period (at least 4 runs per 6 day period). Each vial was returned to refrigerated temperature (2-8°C) between analysis periods. All lots performed as expected, with parameter recovery within the established assay ranges.

**Closed vial stability:** Three lots were set up to verify performance throughout the 34 day expiration date at refrigerated temperature (2-8°C). Each lot number was run at least one time each week for 34 days. No significant trends occurred and there was consistent recovery of values within the indicated assay range.

*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 user is directed to refer to the product assay sheet accompanying the product insert. Expected range values assigned to the assay represent variation between analyzers and established product performance characteristics.

**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.