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

A. 510(k) Number:

K053362

B. Purpose for Submission:

To obtain clearance for the Streck Cell-Chex Auto Control

C. Measurand:

Red Blood Cells

White Blood Cells

D. Type of Test:

Quality Control Material

E. Applicant:

Streck

F. Proprietary and Established Names:

Cell-Chex Auto

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

JPK

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

   The Streck Cell-Chex Auto control is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The Streck Cell-Chex Auto is an assayed, tri-level control formulated with stabilized suspension of human red blood cells and simulated white blood cells in a solution containing biological salts and anti-microbial preservatives. The control is packaged in plastic vials containing 4 ml. Level 1 is a very low concentration, Level 2 a low concentration, and Level 3 a high concentration. Vials are packaged in six or twelve vials.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Streck iQ® Body Fluids Control

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

   K051706

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Composition	Assayed control mixture of red and white blood cells	same
Stability	30 days open vial stability	same

Differences		
Item	Device	Predicate
Stability	75 days closed vial stability	159 days closed vial stability

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

L. Test Principle:

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Reproducibility studies were performed on 2 lots of each level of Streck Cell-Chex Auto Control. 10 consecutive analysis was performed on a single vial of each level. Levels 1, 2, and 3 were tested on 4 different instruments. Levels 2 and 3 were tested on 5 different instruments. Mean, SD and %CV was calculated and found to be acceptable.

b. *Linearity/assay reportable range:*

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

Testing was set up to verify the 30 day open vial dating and 75 day expiration dating. For open vial stability testing, 1 vial of each level, from 2 lots was analyzed on 5 instruments (4 for Level 1), at least twice a week. On days that analysis did not occur, the vials were warmed to room temperature, inverted to mix, and then returned to refrigerated storage. Both lots performed as expected with parameter recovery within the established assay ranges.

The 75 day expiration dating testing was set up similarly, with analysis performed on each vial at least to times per week from the ship date to the expiration date. Between analysis, each vial was returned to refrigerated storage. No significant trends occurred and there was consistent recovery of values within the indicated assay range.

d. *Detection limit:*

e. *Analytical specificity:*

f. *Assay cut-off:*

2. Comparison studies:

a. *Method comparison with predicate device:*

b. *Matrix comparison:*

3. Clinical studies:

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

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

Product samples were provided to 5 off-site laboratories. Results demonstrated all three levels performed within the assay ranges.

4. Clinical cut-off:

5. Expected values/Reference range:

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, based on a Tier 1 review.