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

A. 510(k) Number:

K090137

B. Purpose for Submission:

New Device

C. Measurand:

Low level Quality Control with Nucleated red Blood cells (NRBC)

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

STaK-Chex Plus Retics

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625 Hematology Quality Control mixture

2. Classification:

   Class II

3. Product code:

   GLQ, Mixture, Control, White Blood and Red-Cell Indices

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

   STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated procedures that measure blood cell parameters.

2. Indication(s) for use:

   STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated procedures that measure blood cell parameters.

3. Special conditions for use statement(s):

   Not Applicable

4. Special instrument requirements:

   Not Applicable

I. Device Description:

STaK-Chex Plus Retics is a stabilized suspension of human red blood cells, a nucleated red blood cell analog, a white blood cell component consisting of human and non-human analogs and a platelet component consisting of a non-human analog in a preservative medium. This product is packaged in plastic vials containing 4.5ml. The closures are polypropylene screw caps with polyethylene liners. There are three different levels (low, normal and high). The vials will be packaged in a six (6) or twelve (12) welled vacuum formed "clam–shell" container with the package insert/assay sheet. The product must be stored at 2 – 10° C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   STaK-Chex Plus Retics, Streck, Inc.

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

   K992887

3. Comparison with predicate:

Differences		
Item	Device	Predicate
Intended Use	STaK-Chex Plus Retics is an assayed whole blood control for evaluating the accuracy and precision of automated procedures that measure blood cell parameters.	STaK-Chex Plus Retics is intended to be used as a control for complete blood cell count (CBC), white cell 5-part differential, and reticulocyte parameters on Beckman Coulter GenS series hematology instruments.
Contents (Reagents)	Low Level – Stabilized human and animal blood, plus a nucleated red blood cell analog, Normal and High Levels same as Predicate	Stabilized human and animal blood
Closed Vial Stability	75 days	105 days

Similarities		
Item	Device	Predicate
Open Vial Stability	14	14
Storage Conditions	2-10° C	2-10° C

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

Not Applicable

L. Test Principle:

Laboratories require assayed material for quality control of automated procedures that measure whole blood parameters. Daily use of this whole blood control provides quality control data for confirming the precision and accuracy of instrument operation protocols. Use of stabilized cell preparations for controlling laboratory testing protocols is an established procedure. When handled like a patient sample and assayed on a properly calibrated and functioning instrument this whole blood control will provide values within the expected range indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility Data: Ten consecutive instrument runs performed on the same analyzer with a single vial of control. Resulting product performance data compared to the parameter specific assay ranges. The review of the data was within acceptable limits.

b. Linearity/assay reportable range:

Not Applicable

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

Open Vial Stability: : A minimum of 14 days stability @ 2- 10°C is required to substantiate the closed vial stability claim. The review of the data was within acceptable limits.

Closed Vial Stability: A minimum of 75 days stability @ 2- 10°C is required to substantiate the closed vial stability claim. The review of the data was within acceptable limits.

Value Assignment: The STaK-Chex Plus Retics (with nRBC) product is manufactured and assigned based on instrument specific requirements. A minimum of three vials per level are tested on the Beckman Coulter LH750, LH500 instruments. Each vial is tested for a minimum of three test events performed on different dates. Referees are requested to run each vial in duplicate on the instrument application consecutively. The data is entered into the validated QC link database program which calculates mean, standard deviation, and coefficient of variation for each parameter analyzed. Final assay assignment values are determined using the data collected and established product performance characteristics. Expected range values assigned to the assay are based on the standard deviation of the assay data.

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:

   Not Applicable

N. Proposed Labeling:

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

O. Conclusion:

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