510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k110718

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Assayed control for Red Blood Cells (RBC), White Blood Cells (WBC), Neutrophils (NEUT) %, Lymphocytes (LYM)%, Monocytes (MONO) %, Eosinophils (EOS) %, and Basophils (BASO) %, Mononuclear %, Polymorphonuclear %, Calcium Pyrophosphate Dihydrate (CPPD) Crystals.

D. Type of Test:
Quantitative and Qualitative

E. Applicant:
Streck Inc.

F. Proprietary and Established Names:
Cell-Chex™ with CPPD Crystals

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 Cell and Red Cell Indices
4. Panel:
   81 (Hematology)

H. Intended Use:

1. Intended use(s):
   Cell-Chex™ with CPPD Crystals is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples are including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains calcium pyrophosphate dihydrate CPPD crystals which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex™ with CPPD Crystals is also intended for monitoring white blood cell differentiation (Mononuclear and Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes, and Monocytes) in body fluid samples performed using Cytospin® smears.
2. Indication(s) for use:
   Same as intended use
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   Not applicable

I. Device Description:

Cell-Chex™ with CPPD Crystals is a stabilized suspension of human red blood cells (RBC), human white blood cells (WBC) and calcium pyrophosphate dihydrate (CPPD) crystals (Level 1 only) in a preservative medium. The product is packaged in glass vials containing 2.0 mL. There are two different levels - Level 1 contains a low cell count and CPPD crystals and Level 2 contains a high cell count and no crystals.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Cell-Chex™
2. Predicate K number(s):
   k101335
3. Comparison with predicate:

Similarities		
Item	Cell-Chex™ with CPPD Crystals	Cell-Chex™ (predicate)
Intended Use	Cell-Chex™ with CPPD Crystals is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples are including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains calcium pyrophosphate dihydrate crystals which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex™ with CPPD Crystals is also intended for monitoring white blood cell differentiation (Mononuclear and Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes, and Monocytes) in body fluid samples performed using Cytospin® smears.	Cell-Chex is an assayed control intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid including pleural, pericardial, peritoneal and synovial fluid. Level 1 contains monosodium urate crystals which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex is also intended for monitoring white blood cell differentiation (Mononuclear, Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes and Monocytes) in body fluid samples performed using Cytospin® smears.
Final Product Form	There are two different levels. The product is packaged in glass vials containing 2 mL. The vials are packaged in a 6 or 12 welled vacuum formed “clam shell” container with instructions for use and assay sheet.	Same
Open vial stability	30 days when stored at 2 – 10°C	Same
Closed vial stability	60 days when stored at 2 – 10°C	Same

Differences		
Item	Cell-Chex™	Cell-Chex™ (predicate)
Reagents	Stabilized human red blood cells and human white blood cells in a preservative medium. Level 1 contains calcium pyrophosphate dihydrate (CPPD) crystals.	Stabilized human red blood cells and human white blood cells in a preservative medium. Level 1 contains monosodium urate crystals.

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

CLSI EP05-A2, Evaluation of Precision of Quantitative Measurement Methods; Approved Guidelines-Second Edition.

L. Test Principle:

Cell-Chex™ with CPPD crystals is an in-vitro diagnostic product used for quality control procedures associated with body fluid counting protocols. Total cell counts and crystal identification are performed with a hemocytometer using undiluted or diluted body fluid. Crystal analysis can be performed using light or polarized light microscopy following routine lab protocol for crystal identification. Differential cell counts of body fluids are performed using Cytospin® smears stained by means of routine hematology staining techniques.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

- Run-to-run repeatability: Data was produced from 10 consecutive runs on three lots of each control level on both the hemacytometer and Cytospin®. Results fell within parameter specific assay value assignment ranges and are reflective of ±3SD for the WBC differential parameters and ±2SD for the red and white blood cell parameters. Level 1 results were positive for crystals. Level 2 results were negative for crystals.
- Precision performance: Data was collected internally and at six external sites in accordance with the product's instructions for use (IFU) using the hemacytometer and Cytospin®. One lot of control was run for 20 days (4 reps/day) over the course of 45 days. The results fell within parameter specific assay value assignment ranges and are reflective of ±3SD for the WBC differential parameters and ±2SD for the red and white blood cell parameters. Level 1 results were positive for crystals. Level 2 results were negative for crystals.

b. Linearity/assay reportable range:

Not applicable

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

- Value assignment: Specific to each lot and level of control, a total of five vials were analyzed in duplicate. The assigned values of the total cell counts are based on the average number of cells per µL counted in the nine large square grids on both sides of the Neubauer Improved hemocytometer counting chamber. The assigned value of the differential cell counts are based on replicate 100-cell differentials. A cumulative mean, standard deviation and %CV were calculated for all measurands reported using Cell-Chex™ with CPPD Crystals with the hemacytometer

and Cytospin® platforms. Crystals were identified as "positive" if observed microscopically. The parameter specific assay value assignment ranges are reflective of ± 3SD for the WBC differential parameters and ±2 SD for the RBC and WBC parameters.

- Open vial stability: Three separate lots were analyzed to verify performance throughout the proposed 30 day open vial dating. At each testing interval the vials of control were analyzed one time with the hemacytometer and Cytospin®. On non-testing days, all vials of control were removed from 2-10°C storage, equilibrated to room temperature and mixed in accordance with the IFU. The results fell within parameter specific assay value assignment ranges and are reflective of ±3SD for the WBC differential parameters and ±2SD for the red and white blood cell parameters. Level 1 results were positive for crystals. Level 2 results were negative for crystals.
- Closed vial stability: Three separate lots were analyzed to verify performance throughout the 60 day expiration dating. At, each testing interval the control materials were removed from 2-10°C storage, equilibrated to room temperature, re-suspended and analyzed using both the hemacytometer and Cytospin™. The results fell within parameter specific assay value assignment ranges and are reflective of ±3SD for the WBC differential parameters and ±2SD for the red and white blood cell parameters. Level 1 results were positive for crystals. Level 2 results were negative for crystals.

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 expected value for this control is lot specific as specified by the value assignment procedure. A value assignment sheet is provided with the Package

Insert accompanying the product. It is recommended that each laboratory establish its own expected mean.

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.