510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k101335

B. Purpose for Submission:
Clearance of a new device with a 5-part differential for WBC and ability to detect crystals in synovial fluid. This device will replace the currently cleared Cell-Chex™ and will have the same trade name.

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 %, Monosodium Urate Crystals.

D. Type of Test:
Quantitative and Qualitative

E. Applicant:
Streck Inc.

F. Proprietary and Established Names:
Cell-Chex™

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™ 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 including pleural, pericardial, peritoneal and synovial fluid. Level 1contains 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 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(s)
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   Not applicable

I. Device Description:

Cell-Chex™ is a stabilized suspension of human red blood cells (RBC), human white blood cells (WBC) and monosodium urate crystals (Level 1 only) in a preservative medium. In addition, Level 1 contains a low cell count and Level 2 contains a high cell count.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Cell-Chex™
2. Predicate K number(s):
   k000076
3. Comparison with predicate:

Similarities		
Item	Cell-Chex™	Cell-Chex™ (predicate)
Intended Use	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 including pleural, pericardial, peritoneal and synovial fluid.	Same
Final Product Form	There are two different levels. The product is packaged in glass vials containing 2 mL. The vials are packaged in a six (6) or twelve (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

Differences		
Item	Cell-Chex™	Cell-Chex™ (predicate)
Analytes	Detects crystals in synovial fluid Provides 5-part differential for WBC (Neutrophils, Eosinophils, Basophils, Lymphocytes, and Monocytes) in body fluid samples performed using Cytospin® smears	Does not detect crystals in synovial fluid Does not provide 5-part differential for WBC in body fluids
Reagents	Level 1 contains monosodium urate crystals	No monosodium urate crystals
Closed vial stability	60 days when stored at 2-10°C	6 months when stored at 2-10°C

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

CLSI, Evaluation of Precision of Quantitative Measurement Methods; Approved Guidelines-Second Edition (EP5-A2).

L. Test Principle:

Cell-Chex™ is an in-vitro diagnostic product that is used for quality control

procedures associated with body fluid counting protocols. Total cell counts are performed with a hemocytometer. Crystal analysis can be performed using light or polarized light microscopy. 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 reproducibility: Streck produced data from 10 consecutive runs on three lots of each control level on 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.

   Precision performance: Data was collected internally and at external sites. Streck selected eight external sites to run a single lot of Cell-Chex control in accordance with the product's instructions for use (IFU) using the hemacytometer and Cytospin®. Cell-Chex control materials were stored by the external sites and handled in accordance with the IFU. The controls were run between 14-17 times over the course of several weeks. 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. A cumulative mean, standard deviation and %CV were calculated for all measurands reported using Cell-Chex™ 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: 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. Three separate lots were analyzed to verify performance throughout the proposed 30 day open vial dating. 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: The control vials were analyzed 10-15 times over the

course of 60 days. Control vials were then analyzed once using both the hemacytometer and Cytospin™. Three separate lots were set up to verify performance throughout the 60 day expiration dating. 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: Not applicable

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.