510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k101578

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Red Blood Cells (RBC), White Blood Cells (WBC)

D. Type of Test:
Quality Control Material-Assayed

E. Applicant:
R&D Systems Inc.

F. Proprietary and Established Names:
Body Fluid-I Hematology Control

G. Regulatory Information:

1. Regulation section:
   21 CFR §864.8625 Hematology quality control mixture
2. Classification:
   Class II
3. Product code:
   JPK, Mixture, Hematology Quality Control
4. Panel:
   81 (Hematology)

H. Intended Use:

1. Intended use(s):
   The R&D Body Fluid-I Control is an assayed hematology control intended to monitor the reliability of hematology instruments that quantitatively measure red and white blood cell counts in cerebrospinal fluids, serous fluids, and synovial fluids.
2. Indication(s) for use:
   Same as Intended use
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   Coulter® LH-700 Series

I. Device Description:

The R&D Body Fluid-I Control is composed of human erythrocytes and bovine leukocytes in a plasma-like fluid with preservatives. Three levels are available and each level of control is packaged in a tube containing 3 mL of the control material.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):
   Streck Cell-Chex™ Auto Hematology Control (k053362)
2. Comparison with predicate:

Similarities		
Item	R&D Systems Body Fluid-I Hematology Control	Streck Cell-Chex™ Auto Hematology Control (predicate)
Intended Use Statement	The R&D Body Fluid-I Control is an assayed hematology control intended to monitor the reliability of hematology instruments that quantitatively measure red and white blood cell counts in cerebrospinal fluids, serous fluids, and synovial fluids.	Same
Closed vial stability	75 days	Same
Open vial stability	30 days	Same

Differences		
Item	R&D Systems Body Fluid-I Hematology Control	Streck Cell-Chex™ Auto Hematology Control (predicate)
Manufacturing process	Body Fluid-I is composed of human red blood cells and bovine white blood cells in a plasma-like fluid with preservatives.	Cell-Chex Auto is formulated with stabilized suspension of human red blood cells and simulated white blood cells in a solution containing biological salts and preservatives.
Storage	2-8°C	2-10°C
Analyzers	Coulter® LH-700 Series	Abbott Cell-Dyn ® 3200, 4000, Sapphire™, Beckman Coulter® LH 750, Sysmex XE-2100™
Final Product Form	Three vials (Level 1, 2, and 3) in tubes containing 3 mL of control material	Three vials (Level 1, 2, and 3) in plastic vials containing 4 mL of control material

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

Not applicable

L. Test Principle:

Body Fluid-I Control is an *in vitro* diagnostic product that provides a means of monitoring the accuracy and precision of body fluid WBC and RBC counts performed on automated hematology blood cell counters.

M. Performance Characteristics:

1. Analytical performance:

   a. Precision/Reproducibility:

   R&D Systems Body Fluid-I control reproducibility studies were conducted at three locations, employing three separate lots run in duplicate, with two runs per day for 20 operating days. Each location used its own Beckman Coulter

LH750 to run one lot containing 3 levels of control. The results for the study are as follows:

WBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	15.4	7.1	6.3
Level 2	3.0	6.7	3.0
Level 3	1.8	1.9	2.0
RBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	3.8	3.8	4.2
Level 2	1.5	1.6	1.6
Level 3	0.7	0.7	0.7

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 four vials are analyzed in duplicate. A cumulative mean and standard deviation (SD) are calculated for each measurand reported. The assay ranges are set at ±2SD for level 1 RBC and WBC. Level 2 and level 3 RBC and WBC ranges reflect ±3SD.

Open Vial Stability: Three lots of control material each containing 3 levels were tested near the end of their closed vial shelf life for the purpose of evaluating open vial stability. The controls were stored at 2 - 8°C until they were tested. Over the course of 30 days the control was analyzed 9 to11 times. The results for the study are as follows:

WBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	12.0	8.9	9.2
Level 2	5.1	4.3	4.5
Level 3	2.1	3.7	3.0
RBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	10.2	9.2	8.2
Level 2	10.2	3.3	3.1
Level 3	1.5	1.3	1.5

Closed Vial Stability: For the purpose of evaluating closed vial stability, three lots of control material each containing 3 levels were tested 23-26 times over the course of 75 days. The results for the study are as follows:

WBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	15.5	20.3	14.4
Level 2	4.7	10.3	4.8
Level 3	2.6	7.4	2.4
RBC	**Lot 1 %CV**	**Lot 2 %CV**	**Lot 3 %CV**
Level 1	9.6	5.8	4.5
Level 2	2.7	2.4	4.8
Level 3	1.2	1.0	1.0

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:
   Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Expected values are provided in the Package Insert accompanying the product.

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.