510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k091433

B. Purpose for Submission:
To obtain clearance for the Retic-I Plus Hematology Control

C. Measurand:
IRF and Absolute Reticulocyte

D. Type of Test:
Assayed controls; automated cell counter

E. Applicant:
R&D Systems, Inc.

F. Proprietary and Established Names:
R&D Systems Retic-I Plus 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:
   Hematology 81

H. Intended Use:

1. Intended use(s):
   R&D Retic-I Plus Control is a tri-level, assayed hematology control designed to monitor values obtained from automated reticulocyte counting methods.
2. Indication(s) for use:
   Same as Intended Use
3. Special conditions for use statement(s):
   Not Applicable
4. Special instrument requirements:
   Not Applicable

I. Device Description:
R&D Systems Retic-I Plus Hematology Control is an in vitro diagnostic reagent composed of human and avian erythrocytes in a plasma-like medium with preservatives. It is composed of stabilized materials that provide a means of monitoring automated reticulocyte counting methods. It is sampled in the same manner as a patient specimen. There are three different levels (Low-level 1, Normal-level 2 and High-level 3) available and each control is packaged in a tube containing 4 mL of the control material. The product must be stored at 2° – 8°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   R&D Systems Advia Retic Plus Hematology Control
2. Predicate K number(s):

k010461

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	R&D Retic-I Plus Control is a tri-level, assayed hematology control designed to monitor values obtained from automated reticulocyte counting methods.	Same
Open Vial Claim	2° – 8°C (14 days)	2° – 8°C (14 days)
Closed Vial Claim	2° – 8°C (75 days)	2° – 8°C (75 days)
Analytes	Retic%, MCVr, RBC	Retic%, MRV, RBC

Differences		
Item	Device	Predicate
Analytes	Immature Reticulocyte Fraction (IRF), Retic# (Retic x 10^6/uL)	MCVg, CHCMg, CHCMr, CHg, CHr

*MCVr = MRV, mean corpuscular volume of reticulocytes

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

Points to consider: Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material, February 3, 1999.

L. Test Principle:

Controls are comprised of stabilized materials that provide a means of monitoring the performance of reticulocyte counting methods in accordance with established laboratory practice to monitor the performance of diagnostic tests. It is sampled in the same manner as a patient specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility: Reproducibility data was taken from the stability data. Three levels of control material were tested for a minimum of 3 times/day over a 3 to 5 day period. The CV% for each lot and level are reflected below:

	Level 1	Level 2	Level 3
Lot 1	6.14	0.93	0.84
Lot 2	5.95	0.75	0.75
Lot 3	7.58	0.97	0.71

b. Linearity/assay reportable range:

Not Applicable

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

Open Vial Stability: To validate open vial stability one vial from each lot and each level were run during a 14 day period. The ranges established for acceptance criteria were Level 1 mean ± 0.20, Level 2 mean ± 0.10 and Level 3 mean ± 0.10. To meet acceptance criteria, all results were to be within the

range throughout the 14 days of testing. All results were within range and no significant changes in mean or variability were observed.
Value Assignment was determined by analyzing an average of the minimum and maximum values of three lots run on the Coulter LH750 and GENS. This method was utilized because all testing was performed on in-house instruments.

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.