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

A. 510(k) Number:

K072268

B. Purpose for Submission:

New Device

C. Measurand:

White Blood Cells (WBC**)**

D. Type of Test:

Quantitative

E. Applicant:

R&D Systems, Inc.

F. Proprietary and Established Names:

HC WBC Control

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology Quality Control Material

2. Classification:

   Class II

3. Product code:

   JPK

4. Panel:

   81 (Hematology)

H. Intended Use:

1. Intended use(s):

   HC WBC Hematology control is an assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood.

2. Indication(s) for use:

   It is established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. The HC WBC Hematology Control is designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood.

3. Special conditions for use statement(s):

   Not applicable.

4. Special instrument requirements:

   For use on the WBC HemoCue Analyzer

I. Device Description:

The HC WBC Hematology Control is an in-vitro diagnostic control composed of human erythrocytes and bovine leukocytes in a plasma-like fluid with preservatives. It is an assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood. It is sampled in the same manner as a patient sample. It is supplied in a set of three vials (Low, Normal and High) 2 mL each.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CBC-3K Hematology Control

2. Predicate K number(s):

   K904464

3. Comparison with predicate:

Similarities		
Item	***HC WBC Hematology Control***	***CBC-3K Hematology Control***
Intended Use	An assayed whole blood control designed to monitor values obtained from analyzers that measure white blood cell counts in whole blood.	An assayed whole blood control designed to monitor values on multi parameter hematology cell counters.
Base Matrix	Composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma-like fluid with preservatives.	Composed of human erythrocytes and mammalian leukocytes suspended in a plasma-like fluid with preservatives.
Biological Sources	Human and Bovine	Human, Bovine, Porcine, Ostrich
Form	Whole Blood	Same
Open Vial Stability	14 days	Same
Storage	2 C to 8 C until expiration date (105 days)	Same

Differences		
Item	***HC WBC Hematology Control***	***CBC-3K Hematology Control***
Analytes	WBC Only	WBC plus: RBC, HGB, HCT,MCV, MCH, MCHC, RDW, Nuet%, Eos%, Mono%, Lymph%, PLT, MPV

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

Not applicable.

L. Test Principle:

It is established laboratory procedure to use stable controls to monitor the performance of diagnostic tests. This control is composed of stable materials that provide a means of monitoring the performance of hematology blood cell counters. It is sampled in the same manner as a patient specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Two to four runs were completed on two analyzers every fourteen days for all three levels of control (3 lots) for 15 – 18 weeks. The goal was to ensure the reproducibility of the control throughout the shelf life of 105 days. The CV values for all three levels were < 5.5%.

   b. Linearity/assay reportable range:

   Not applicable

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

   Assay value assignment:

   Two HemoCue WBC analyzers were used for analyte assignment and stability testing. The target values are chosen to span the expected medically relevant decision points as well as to incorporate user needs. The Low Level means is targeted at 2.7 – 3.3 x 10^3/µL, the Normal Level is targeted at 7.7 – 8.5 x 10^3/µL and the high level mean is targeted at 20.0 – 24.0 x 10^3/µL. The HC WBC Control Value assignment protocol is based on current R&D assay ranges for the same or similar instrumentation on other R&D products and competitor's assay ranges for the same instrument.

   The number of repetitive runs is determined by a protocol that is based on the reproducibility of that particular analyzer. Samples are analyzed throughout the process for quality control checks. The product is assayed over a two-day period, using two analyzers, two vials, and each sample run in duplicate.

   Closed Vial Stability: Three lots of control material (low, normal, high) were stored at 2 – 8^o C and tested at real time points on two instruments. All data points were within the established range and no significant changes in the mean or variability. Expiration dating reflects the validated time period that assures adequate performance throughout shelf life of 105 days.

   Open Vial Stability: Three lots of control material (low, normal, high) were tested at the end of their shelf life. The lots were stored at 2 – 8^o C. One lot has been evaluated through 14 days. No significant changes in the mean or variability were observed. Two lots, nearing the end of their shelf life, will be validated before release to support the label claim of 14 days.

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 target values are chosen to span the expected medically relevant decision points as well as to incorporate user needs. The Low Level means is targeted at 2.7 – 3.3 x 10^3/µL, the Normal Level is targeted at 7.7 – 8.5 x 10^3/µL and the high level mean is targeted at 20.0 – 24.0 x 10^3/µL.

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.