

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K060464

B. Purpose for Submission:

The parameter RDW-SD (Red Cell Distribution Width-Standard Deviation) is being added to the Coulter 5C Cell Control.

C. Manufacturer and Instrument Name:

Beckman Coulter, Inc., Coulter 5C Cell Control is intended to be used on a new automated hematology analyzer called the Coulter LH780 which will be capable of analyzing the RDW-SD parameter.

D. Type of Test or Tests Performed:

Coulter 5C Cell Control is a quality control material for the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, Ly%, Mo%, Ne%, Eo%, Ba%, Ly#, Mo#, Ne#, Eo#, and Ba#.

E. System Descriptions:

1. Device Description:

5C Cell Control is a hematology quality control mixture intended to be used with automated cell counters and differential cell counters. It is prepared from stabilized human blood so that repeated measurements by an automated cell counter, or differential cell counter, can be made to monitor instrument daily performance. 5C Cell Control consists of treated stabilized human erythrocytes, a stabilized platelet sized component, and fixed erythrocytes that simulate leukocytes. Three levels of varying component concentrations (Abnormal II, Abnormal I, and Normal) are offered.

2. Principles of Operation:

N/A

3. Modes of Operation:

N/A

4. Specimen Identification:

N/A

5. Specimen Sampling and Handling:

N/A

6. Calibration:

N/A

7. Quality Control:

5C Cell Control has assigned values and expected ranges which can be used to monitor instrument performance.

8. Software: N/A

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes_____ or No_____

F. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

JPK

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

5C Cell control is a hematology quality control mixture used to monitor the performance of coulter hematology analyzers listed on the Table of Expected Results in conjunction with specific Coulter reagents. The assigned values and expected ranges on the Table of Expected Results can be used to monitor instrument performance.

2. Special Conditions for Use Statement(s):

N/A

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

COULTER® 5C® Cell Control, K912133 (cleared as COULTER® PX Cell Control)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Product Description	5C Controls consist of treated, stabilized human erythrocytes in an isotonic, bacteriostatic medium. It also contains a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.	Same
Intended Use	5C Cell Control is a hematology quality control mixture used to monitor the performance of Coulter hematology analyzers listed on the Table of Expected Results in conjunction with specific coulter reagents. The assigned values and expected	Same

Similarities		
Item	Device	Predicate
Cellular Populations	<p>ranges on the Table of Expected Results can be used to monitor instrument performance.</p> <p>Erythrocytes, platelets, lymphocytes, monocytes, neutrophils, and eosinophils.</p>	Same
Manufacturing Process	<p>5C Cell Control is prepared from pre-screened units of whole human blood as well as animal blood. Stabilized RBC and platelet pools and fixed lymphocyte, monocyte, neutrophil, and eosinophils pools are manufactured independently. These pools are combined to provide the desired target ranges.</p>	Same
Sample Preparation	<p>No special sample preparation is required. The control is a ready to use product. The control is warmed to ambient temperature, mixed by hand and analyzed on specified hematology analyzers.</p>	Same
Final Product Form	<p>Three levels, liquid, ready to use.</p>	Same
Open Vial Stability	<p>13 events over 13 days when stored at 2-8° C.</p>	Same
Closed Vial Stability	<p>95 days when stored at 2-8° C.</p>	Same

Differences		
Item	Device	Predicate
Assayed Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, PCT, PDW, Ly%, Mo%, Ne%, Eo%, Ba%, Ly#, Mo#, Ne#, Eo#, Ba#	Same with the additional parameter RDW-SD.

I. Special Control/Guidance Document Referenced (if applicable):

N/A

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

N/A

b. Precision/Reproducibility:

N/A

c. Linearity:

N/A

d. Carryover:

N/A

e. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

For Open Vial Stability and Closed Vial Stability, a total of nine lots of 5C Controls were tested through expiration starting near the end of the product's shelf life. Two tubes per level (3) were evaluated. Open Vial Stability was determined to be 13 events over 13 days when stored at 2-8° C. Closed Vial Stability was determined to be 95 days when stored at 2-8° C.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

