

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

**A. 510(k) Number:**

K082162

**B. Purpose for Submission:**

Clearance of new device

**C. Measurand:**

Erythrocytes, Monocytes, Lymphocytes

**D. Type of Test:**

Quality Control Material

**E. Applicant:**

Beckman-Coulter INC

**F. Proprietary and Established Names:**

Coulter Body Fluid Control

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

JPK

4. Panel:

81 Hematology

**H. Intended Use:**

1. Intended use(s):

The Beckman-Coulter Body Fluid Control is a hematology quality control material used to monitor the performance and verify the measuring range of the body fluid cycle of the UniCel® DxH 800 COULTER Cellular Analysis System.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

UniCel® DxH 800 COULTER Cellular Analysis System (K081930)

**I. Device Description:**

The Beckman-Coulter Body Fluid Control is a hematology quality control mixture intended to be used with the UniCel® DxH 800 COULTER Cellular Analysis System (K081930). It consists of 3 levels of treated, stabilized human erythrocytes, a stabilized platelet-sized component, and fixed erythrocytes that simulate leukocytes. The platelet-sized components are not assayed nor reported in the body fluid cycle.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

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

2. Predicate 510(k) number(s):

K912133, K060464

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended Use	Quality control material intended to monitor the performance of a hematology analyzer	same
Product composition	Treated, stabilized human erythrocytes in an isotonic medium, and stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes	same
Levels	3 levels	same

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Cellular Population	Erythrocytes, Platelets, Lymphocytes, and monocytes	Erythrocytes, platelets, lymphocytes, monocytes, neutrophils, and eosinophils
Assayed Parameters	RBC and TNC	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, Ly%, Mo%, Ne%, Eo%, Ba%, Ly#, Mo#, Ne#, Eo#, Ba#
Analyzers	UniCel® DxH 800	COULTER® LH 780, LH 750, GENS*S, STKS, LH 500, HmX, HmX w. Autoloader, MAXM, & MAXM w. Autoloader

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

**L. Test Principle:**

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Body Fluids Level 1

% CV		
	RBC	TNC
Lot 1	4.0	8.3
Lot 2	4.1	10.2
Lot 3	4.2	9.2

Body Fluids Level 2

% CV		
	RBC	TNC
Lot 1	0.6	1.8
Lot 2	0.6	1.9
Lot 3	0.9	1.8

Body Fluids Level 3

% CV		
	RBC	TNC
Lot 1	1.2	1.3
Lot 2	1.1	1.4
Lot 3	1.2	1.1

b. *Linearity/assay reportable range:* N/A

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

The product was evaluated for real-time open and closed vial stability.

d. *Detection limit:* N/A

e. *Analytical specificity:* N/A

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

N/A

b. *Clinical specificity:*

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

**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.

