

**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:

Similarities		
Item	Device	Predicate
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

Differences		
Item	Device	Predicate
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.

