

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

A. 510(k) Number:

K072846

B. Purpose for Submission:

Traditional submission for a new device.

C. Measurand:

WBCs and RBCs in cerebrospinal fluid (CSF) using hematology analyzers.

D. Type of Test:

Differential cell count of human spinal fluid

E. Applicant:

R & D Systems, Inc.

F. Proprietary and Established Names:

CSF Automated Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

JPk

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

CSF Automated Control is an assayed control designed to monitor values obtained using hematology instruments that measure CSF samples.

2. Indication(s) for use:

N/A

3. Special conditions for use statement(s):

N/A

4. Special instrument requirements:

N/A

I. Device Description:

CSF Automated Control is an in vitro diagnostic reagent composed of human erythrocytes and bovine leukocytes suspended in a cerebrospinal like fluid with preservatives. It is an assayed whole blood control designed to monitor values obtained using hematology instruments that measure CSF (cerebro spinal fluid) samples.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Diagnostics ADVIA TESTpoint™ CSF Controls

2. Predicate K number(s):

K022968

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Whole Blood	Same
Storage (unopened)	2° C to 8° C until expiration date	Same

Similarities		
Item	Device	Predicate
Stabilizers	Contains stabilizers	Same
Analytes	Level 1-WBC and RBC Level 2-WBC, RBC, % Neut, % % Lymph, % Mono, % Eos, % Mononuclear cell count, % Polymorphonuclear cell count	Same

Differences		
Item	Device	Predicate
Intended Use	Intended to monitor values obtained using hematology instruments that measure CSF samples. Refer to assay table for specific instrument models.	Intended to monitor the precision and accuracy of ADVIA 120 Hematology Systems when analyzing CSF samples.
Base Matrix	Composed of human erythrocytes and bovine leukocytes suspended in a cerebrospinal like fluid with preservatives.	Composed of red blood cells and white blood cells derived from human sources stored in a stabilizing medium.
Open Vial Claim	14 days	10 days

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

N/A

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

N/A

b. Linearity/assay reportable range:

N/A

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

N/A

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):

Expiration dating is established at 105 days (closed vial) and 14 days (open vial) when stored at 2-8° C and handled according to instructions for use. Three lots of two levels were tested for open and closed vial testing.

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

The target mean values for manufacturing are initially specified at 3-7 cells/μL for the WBCs 5-15 cells/μL for the RBCs for level 1, and 180-220 cells/μL for the WBCs, 10-20 % Mononuclears, 70-90% Polymorphonuclears, ~5% Monocytes, and 180-220 cells/μL for the RBCs for level 2. Each different analyzer will have its own protocol to establish ranges.

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.