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

A. 510(k) Number:

K042836

B. Purpose for Submission:

New Device

C. Measurand:

Reticulocyte, Quality Control Material

D. Type of Test:

Not Applicable.

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Reticulocyte Control (A)

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology Quality Control Mixture

2. Classification:

   Class II

3. Product code:

   JPK, Mixture, Hematology Quality Control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   Liquichek Reticulocyte Control (A) is an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.

2. Indication(s) for use:

   Liquichek Reticulocyte Control (A) is an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.

3. Special conditions for use statement(s):

   Not applicable.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

This a fluid product composed of stabilized human red blood cells suspended in a buffered fluid added constituents of animal origin and preservatives. This product is supplied in three levels.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Liquichek Reticulocyte Control

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

   K993496

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Liquichek Reticulocyte Control (A)	***Liquichek Reticulocyte Control***
Intended Use	Used as an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.	Used as a whole blood reference control material designed to verify the precision of COULTER instruments equipped with reticulocyte measuring capabilities using VCS technology, and New Methylene Blue Stain.
Form	Liquid	Same
Storage (Unopened)	2-8^{o}C Until expiration date	2-8^{o}C Until expiration date

Differences		
Item	Device	Predicate
Open Vial Claim	21 days at 2-8^{o}C	31 days at 2-8^{o}C

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

Not Applicable.

L. Test Principle:

Not Applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable.

b. Linearity/assay reportable range:

Not Applicable.

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

Not Applicable.

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):

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

   The reagent insert contains mean values derived from replicate analyses and are specific for the lot of product. The tests listed were performed by using manufacturer supported reagents and a representative sampling of the lot of product. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

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.