

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE**

A. 510(k) Number: k033380

B. Analyte: Calibrator for Acid Phosphatase, Lactate, Lipase and Direct TIBC

C. Type of Test: N/A

D. Applicant: Bayer Healthcare LLC

E. Proprietary and Established Names: Bayer ADVIA 1650 Special Chemistry Calibrator

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1150
2. Classification: Class II
3. Product Code: JIX
4. Panel: 75

G. Intended Use:

1. Indication(s) for use: For *in vitro* diagnostic use in the calibration of the ADVIA 1650 Chemistry system for certain chemistry methods.
2. Special condition for use statement(s): none
3. Special instrument Requirements: Bayer ADVIA 1650

H. Device Description: This device is a Special Chemistry Calibrator for the Bayer ADVIA 1650 Chemistry system. These calibrators are a lyophilized mixture of human serum base to which appropriate nonhuman constituents have been added to achieve specific concentrations and is intended for *in vitro* diagnostic use to calibrate the ADVIA 1650 Chemistry system.

I. Substantial Equivalence Information:

1. Predicate device name(s): Bayer Special Chemistry Calibrator
2. Predicate K number(s): K030804
3. Comparison with predicate:

DEVICE	PREDICATE
A. Similarities	
Stable at 2-8° until expiration on label	Stable at 2-8° until expiration on label
Single levels	Single levels
Lyophilized mixture of human and bovine serum base to which appropriate human constituents have been added to achieve specific concentrations	Lyophilized mixture of human and bovine serum base to which appropriate human constituents have been added to achieve specific concentrations
Bayer Special Chemistry Calibrator is intended for in vitro diagnostic use to calibrate Acid Phosphatase, Lactate, Lipase and Direct TIBC*	Bayer Special Chemistry Calibrator is intended for in vitro diagnostic use to calibrate Acid Phosphatase, Lactate, and Lipase
Stable for seven days when reconstituted according to directions and stored at 2-8° C for Lactate, Lipase and Direct TIBC. Stable 2 days for Acid Phosphatase.	Stable for seven days when reconstituted according to directions and stored at 2-8° C for Lactate, and Lipase. Stable 2 days for Acid Phosphatase.

* The predicate device contained Direct TIBC as an analyte so the manufacturing did not change, however Bayer did not assign values for the Direct TIBC at the time of the predicate device. This submission only includes information relevant to the value assignment of Direct TIBC.

J. Standard/Guidance Document Referenced (if applicable) Guidance for Industry - Abbreviated 510(k) Submissions for InVitro Calibrators

K. Test Principle: N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:* N/A

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

c. *Traceability (controls, calibrators, or method):* The commercial lot of calibrators are value assigned from a “master lot” (stored at -80°C) on the ADVIA 1650 system using the appropriate ADVIA 1650 reagents. Total lot analyte concentration = Ratio (master lot observed mean/Master Lot original assignment)* Test lot observed mean.

d. *Detection limit (functional sensitivity):* 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
4. Clinical cut-off: N/A
5. Expected values/Reference range: N/A

M. Conclusion: Based upon the information provided, I recommend that the Bayer Special Chemistry Calibrators for the ADVIA 1650 Chemistry systems be found substantially equivalent with the predicate devices as defined in 21 CFR 862.1150.