

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

A. 510(k) Number: K031683

B. Analyte: Calibrator for multiple analytes (Ethanol, Acetaminophen, Salicylate and Ammonia)

C. Type of Test: N/A

D. Applicant: Bayer Healthcare

E. Proprietary and Established Names: Bayer Toxammonia 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: Bayer ToxAmmonia calibrator is intended for *in vitro* diagnostic use to calibrate acetaminophen, ammonia, ethanol and salicylate assays on the ADVIA IMS Chemistry systems.
2. Special condition for use statement(s): none
3. Special instrument Requirements: none

H. Device Description: ToxAmmonia Calibrator for the Bayer ADVIA IMS Chemistry systems. These calibrators are a lyophilized mixture of human serum base to which appropriate nonhuman constituents have been added to achieve specific concentrations is intended for in vitro diagnostic use to calibrate acetaminophen, ammonia, ethanol and salicylate assays on the ADVIA IMS Chemistry systems.

I. Substantial Equivalence Information:

1. Predicate device name(s): Bayer SetPoint Chemistry calibrator
2. Predicate K number(s): K030169

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	
B. Differences			
Liquid human serum albumin base to which appropriate nonhuman 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 Toxammonia is intended for in vitro diagnostic use to calibrate acetaminophen, ammonia, ethanol and salicylate assays on the ADVIA IMS chemistry systems		For use as a calibrator of clinical chemistry assays for automated analytical procedures	
Stable for three days when reconstituted according to directions and stored at 2-8° C		Stable for 48 hours when reconstituted according to directions and stored at 2-8° C and protected from light with the exception of Total and direct bilirubin, which are stable for eight hours.	

J. Standard/Guidance Document Referenced (if applicable) Guidance for Industry - Abbreviated 510(k) Submissions for InVitro Diagnostic 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 SSV (System Specific Value) values for the IMS were derived from studies using reference materials. Highly purified analyte was used to prepare standards, which in turn, were used to calibrate an IMS system. This system was then used to establish the SSV for the first Master Lot of product in the nested study.

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 ToxAmmonia Calibrators for the ADVIA IMS Chemistry systems be found substantially equivalent with the predicate devices as defined in 21 CFR 862.1150.