

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

**A. 510(k) Number:**

k061139

**B. Purpose for Submission:**

New device

**C. Measurand:**

PSA and cPSA calibrators

**D. Type of Test:**

Calibrators

**E. Applicant:**

Bayer Diagnostics

**F. Proprietary and Established Names:**

ADVIA® IMS PSA Calibrator and ADVIA® IMS cPSA Calibrator

**G. Regulatory Information:**

1. Regulation section:  
21 CFR §862.1150, Calibrator
2. Classification:  
Class II
3. Product code:  
JIT, Calibrator, Secondary
4. Panel:  
Chemistry (75)

**H. Intended Use:**

1. Intended use(s):  
**ADVIA® IMS PSA Calibrator:** For in vitro diagnostic use in the calibration of quantitative PSA assays on the ADVIA® IMS system.  
**ADVIA® IMS cPSA Calibrator:** For in vitro diagnostic use in the calibration of quantitative complexed PSA assays on the ADVIA® IMS system.
2. Indication(s) for use:  
Same as Intended use.
3. Special conditions for use statement(s):  
For prescription use only.
4. Special instrument requirements:  
ADVIA® IMS system

**I. Device Description:**

The Bayer ADVIA® IMS PSA Calibrator and ADVIA® IMS cPSA Calibrators are prepared in bovine serum with non-serum constituents added. There are six PSA levels each for the ADVIA® IMS PSA and cPSA Calibrators. The levels for PSA Calibrator are 0, 2, 10, 25, 50 and 100 ng/mL. The cPSA Calibrator values are assigned to specific lots and are not assigned specific values.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Lipoprotein Calibrator
2. Predicate 510(k) number(s):

k051619

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Bayer PSA and cPSA calibrators are intended for in vitro diagnostic use to calibrate PSA and cPSA assays on the ADVIA® IMS system	Bayer Lipoprotein calibrators are intended for in vitro diagnostic use to calibrate apolipoprotein A1 and apolipoprotein B assays on the ADVIA® IMS system
Levels	Six levels	same

Differences		
Item	Device	Predicate
Constituent analytes	PSA in the ADVIA® IMS PSA Calibrator and cPSA in ADVIA® IMS cPSA Calibrator	Apolipoprotein A1 Apolipoprotein B HDL Cholesterol
Format	Bovine serum based Liquid form (cPSA calibrators are stored frozen). ready to use.	Mixture of human and bovine serum based Lyophilized
Stability	PSA Calibrators: Stable until the expiration date on the label when unopened and stored at 2-8°C Stable for 30 days when opened and stored at 2-8°C  cPSA Calibrators: Stable until the expiration date on the label when unopened and stored at <= -10°C Stable for 35 days when opened and stored at 2-8°C.	Stable at 2-8°C until the expiration date printed on the label. Stable 3 days when reconstituted and stored at 2-8°C.

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

Abbreviated 510(k) submissions for In Vitro Diagnostic Calibrators.

**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):*  
The ADVIA IMS PSA and cPSA calibrators are traceable to Stanford University prostate specific antigen reference material which consists of 90% purified PSA- $\alpha_1$ -antichymotrypsin (ACT) and 10% free PSA (90:10) mixture on a molar basis.

Stability:

**PSA Calibrators:**

Unopened calibrators are stable when stored at 2-8°C, until the expiration date on the label.

Opened calibrators are stable for 30 days, when stored at 2-8°C.

**cPSA Calibrators:**

Unopened calibrators are stable when stored at  $\leq -10^\circ\text{C}$  in a non frost-free freezer, until the expiration date on the label.

Opened calibrators are stable for 35 days, when stored at 2-8°C.

- 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):*  
Not applicable
4. Clinical cut-off:  
Not applicable.
5. Expected values/Reference range:  
Not applicable.

**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.