

**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- α_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.