510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k061137

B. Purpose for Submission:
New device

C. Measurand:
Controls for complexed PSA (cPSA)

D. Type of Test:
Assayed Quality Control material

E. Applicant:
Bayer Diagnostics

F. Proprietary and Established Names:
Bayer ADVIA® IMS cPSA Controls

G. Regulatory Information:
1. Regulation section:
   21 CFR §862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class I, reserved
3. Product code:
   JJY, Multi-analyte controls, all kinds (assayed and unassayed)
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   For in vitro diagnostic use to monitor the precision and the accuracy of the
   assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer
   Immuno1® systems.
2. Indication(s) for use:
   For in vitro diagnostic use to monitor the precision and the accuracy of the
   assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer
   Immuno1® systems.
3. Special conditions for use statement(s):
   For prescription use only.
4. Special instrument requirements:
   ADVIA® IMS system and Bayer Immuno1® system

I. Device Description:
The Bayer ADVIA® IMS cPSA Controls are bovine serum based with non-serum
constituents added. The analyte in the control material is cPSA. The cPSA control
kit consists of three different levels of control materials. Level 1 control is
manufactured to a clinically significant decision point, between normal and patient
groups. Level 3 control is manufactured to the upper analytical range of the assay.
Level 2 control is manufactured to a level in between Level 1 and Level 3 controls.

J. Substantial Equivalence Information:
1. Predicate device name(s):
Bayer Special Chemistry Controls

2. **Predicate 510(k) number(s):**
   k033379

3. **Comparison with predicate:**

<table>
<thead>
<tr>
<th>Similarities Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td>Bayer ADVIA® IMS cPSA Controls are intended for in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA method on immunoassay systems including the ADVIA® IMS and Bayer Immuno1® systems</td>
<td>Bayer special chemistry controls are intended for in vitro diagnostic use in the control of ADVIA chemistry system for certain chemistry methods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Differences Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constituent analytes</td>
<td>cPSA</td>
<td>Acid phosphatase Lactate Lipase Pancreatic Amylase Cholinesterase Total iron binding capacity</td>
</tr>
<tr>
<td>Format</td>
<td>Bovine serum based with human constituents Liquid form and ready to use.</td>
<td>Human serum based with human and bovine constituents Lyophilized</td>
</tr>
<tr>
<td>Levels</td>
<td>Three levels</td>
<td>Two levels</td>
</tr>
<tr>
<td>Stability</td>
<td>Stable until the expiration date on the label when unopened and stored at &lt;= -10°C. Stable for 35 days when opened and stored at 2-8°C.</td>
<td>Stable at 2-8°C until the expiration date printed on the label. Stable 7 days when reconstituted and stored at 2-8°C.</td>
</tr>
</tbody>
</table>

**K. Standard/Guidance Document Referenced (if applicable):**
Guidance for Industry “Points to consider guidance document on assayed and unassayed quality control material”.
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 cPSA controls are traceable to Stanford University PSA reference material. This standard consists of 90% purified PSA-α₁-
antichymotrypsin (ACT) and 10% free PSA (90:10) mixture on a molar basis. Value assignment of production lots is done by a nested study that uses a Master Lot of product traceable to the Stanford PSA standard.
      Unopened controls are stable when stored at <= -10°C in a non frost-free freezer, until the expiration date on the label. Opened controls 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.