A. 510(k) Number:

k110061

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for unconjugated estriol assay

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics

F. Proprietary and Established Names:

IMMULITE unconjugated Estriol (uE3) Calibration Verification Material

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJX - Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

75 Clinical Chemistry
H. Intended Use:

1. Intended use(s):

   Refer to indications for use below

2. Indication(s) for use:

   For in vitro diagnostic use as a control for calibration verification of the IMMULITE Unconjugated Estriol (uE3) assays on the IMMULITE/IMMULITE 1000 and 2000 systems.

   The calibration verification material is assayed control with four levels. The analyte levels for IMMULITE 1000 are 0.00, 0.016, 2.70, and 11.2 ng/mL and 0.00, 0.19, 2.90, and 12.0 ng/mL for IMMULITE 2000 systems. The matrix is estriol in processed horse serum.

3. Special conditions for use statement(s):

   For in vitro diagnostic use. For prescription use only.

4. Special instrument requirements:

   The IMMULITE Unconjugated Estriol (uE3) Calibration Verification Material (CVM) is intended for use with the IMMULITE/IMMULITE 1000 and 2000 systems.

I. Device Description:

The IMMULITE uE3 CVM consists of one set of four vials, 2 mL each, containing low, intermediate, and high levels of unconjugated estriol in processed horse serum, with preservative. The first level is an unconjugated estriol-free sample. The IMMULITE uE3 CVM levels are supplied in liquid form, ready to use.

<table>
<thead>
<tr>
<th>IMMULITE uE3 CVM</th>
<th>Target Value (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IMMULITE/IMMULITE 1000</td>
</tr>
<tr>
<td>Level 1</td>
<td>0.00</td>
</tr>
<tr>
<td>Level 2</td>
<td>0.16</td>
</tr>
<tr>
<td>Level 3</td>
<td>2.70</td>
</tr>
<tr>
<td>Level 4</td>
<td>11.2</td>
</tr>
</tbody>
</table>

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ADVIA Centaur Enhanced Estradiol (eE2) Master Curve Material
2. Predicate 510(k) number(s):
   
k102904

3. Comparison with predicate:

<table>
<thead>
<tr>
<th>Item</th>
<th>Device (k110061)</th>
<th>Predicate (k102904)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>For use in calibration verification of the assay.</td>
<td>Same</td>
</tr>
<tr>
<td>Format</td>
<td>Liquid, ready for use</td>
<td>Lyophilized</td>
</tr>
<tr>
<td>Matrix</td>
<td>Horse serum</td>
<td>Human serum</td>
</tr>
<tr>
<td>Analyte</td>
<td>Estriol</td>
<td>Estradiol</td>
</tr>
<tr>
<td>Instrument</td>
<td>IMMULITE/IMMULITE 1000, and 2000 systems</td>
<td>ADVIA Centaur XP systems</td>
</tr>
<tr>
<td>Stability</td>
<td>Unopened Store at 2-8°C until expiration date</td>
<td>Unopened</td>
</tr>
<tr>
<td></td>
<td>Opened Use immediately after opening, discard after use</td>
<td>Store at 2-8°C for 14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-8°C for 14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On-board</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 hours</td>
</tr>
<tr>
<td>Levels</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

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

1. Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrator; Final Guidance for Industry.

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):

**Traceability**

The IMMULITE Unconjugated Estriol (uE3) Calibration Verification Material is traceable to an internal reference calibrator. Reference calibrators are traceable to individual human samples assigned with GC-MS values.

**Expected Values and Value Ranges**

Expected values for the IMMULITE uE3 CVM are determined by analyses of 40 replicates at each control level using three kit lots and three systems (IMMULITE/IMMULITE 1000 or IMMULITE 2000 systems). Pre-determined acceptance criteria for analyte recovery must be met for each calibrator lot. Calibrator assigned values are lot dependent as specified in the product labeling.

**Stability**

Stability testing protocols and acceptance criteria for the IMMULITE uE3 CVM were reviewed and found acceptable. The manufacturer claims a shelf life stability of 6 months at the recommended storage temperatures of 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:

The expected values are provided in the labeling for each specific lot.

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.