

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

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

k060359

**B. Purpose for Submission:**

New device

**C. Measurand:**

Calibrators and Controls for Insulin assays

**D. Type of Test:**

Not applicable

**E. Applicant:**

Denka Seiken Co., LTD.

**F. Proprietary and Established Names:**

Architect Insulin Calibrators and Controls

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
<u>Calibrator, Secondary (JIT)</u>	<u>Class II</u>	<u>21 CFR 862.1150, Calibrator.</u>	<u>75 Clinical Chemistry (CH)</u>
<u>Single (Specified) Analyte Controls (Assayed And Unassayed) (JJX)</u>	<u>Class I</u>	<u>21 CFR 862.1660, Quality control material (assayed and unassayed).</u>	<u>75 Clinical Chemistry (CH)</u>

**H. Intended Use:**

1. Intended use(s):

See Indications for use below

2. Indication(s) for use:

**Calibrators**

The Architect Insulin Calibrators are for the calibration of the Architect *i* System when used for the quantitative determination of human insulin in human serum and plasma.

**Controls**

The Architect Insulin Controls are for the verification of the accuracy and precision of the Architect *i* System when used for the quantitative determination of human insulin in human serum or plasma.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Architect *i* System

**I. Device Description:**

**Calibrators**

The Architect Insulin Calibrators consist of six calibrators (A-F). Calibrator A contains acetate buffer. Calibrators B-F contain insulin in acetate buffer. The calibrators are preserved by sodium azide and other antimicrobial agents. Each Insulin Calibrator kit contains 6 bottles of Calibrators (4.0 mL fill volume) at the following Insulin concentrations: 0, 3, 10, 100 and 300  $\mu\text{U}/\text{mL}$ .

**Controls**

The Architect Insulin Controls contain insulin prepared in acetate buffer. The controls are preserved by sodium azide and other antimicrobial agents. Each Insulin Control kit contains 3 bottles of controls (Low, Medium and High) at the following concentrations: 8, 40, and 120  $\mu\text{U}/\text{mL}$ .

**J. Substantial Equivalence Information:**

**Calibrators**

<b>Predicate</b>	<b>k021535</b>
<b>Describe the item being compared</b>	
<b>Bayer ADVIA Centaur and ACS: 180, Insulin Calibrators</b>	

**Controls**

<b>Predicate</b>	<b>k030452</b>
<b>Describe the item being compared</b>	
<b>Bayer Ligand Plus 1, 2, 3 Controls</b>	

**Comparison with Predicate**

<b>Item</b>	<b>Calibrator – Similarities</b>	<b>Predicate</b>
<b>Intended use</b>	Calibration of quantitative assays for human insulin	Same
<b>Method</b>	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
<b>Binding Protein</b>	Insulin	Same
<b>Traceability</b>	WHO Insulin 1 <sup>st</sup> International Reference Preparation 66/304	Same
<b>Calibrator</b>	<b>Calibrator – Differences</b>	<b>Predicate</b>
<b>Platform</b>	Architect <i>i</i> System	ADVIA Centaur or ACS 180
<b>Matrix</b>	Acetate buffer with sodium azide and preservatives	Buffered saline with casein, potassium thiocyanate (3.89%), sodium azide and preservatives
<b>Concentration</b>	6 levels: 0, 3, 10, 30 and 100 µU/mL	2 levels: High & Low

Item	Control – Similarities	Predicate
<b>Intended use</b>	Verification of the accuracy and precision of quantitative assays	Same
<b>Method</b>	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
<b>Binding Protein</b>	Insulin	Same
<b>Levels</b>	Three	Same
Item	Control – Differences	Predicate
<b>Platform</b>	Architect <i>i</i> System	ADVIA Centaur or ACS 180
<b>Matrix</b>	Liquid	Lyophilized
<b>Type</b>	Single analyte (insulin)	Multiple analytes

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

Document Title	Office	Web Page
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft	OIVD	<a href="http://www.fda.gov/cdrh/ode/99.html">http://www.fda.gov/cdrh/ode/99.html</a>
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD	<a href="http://www.fda.gov/cdrh/ode/calibrator.html">http://www.fda.gov/cdrh/ode/calibrator.html</a>

**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 primary calibrators and controls were manufactured from the WHO Insulin 1<sup>st</sup> International Reference Preparation (IRP) 66/304. The Architect Insulin Calibrators and Controls were manufactured by matching to the primary calibrators and controls. Relative light unit (RLU) testing was performed on the Architect i system and RLU values were compared to the corresponding primary calibrators and controls. The sponsor's acceptance criteria: RLU variation between the Architect Insulin Calibrators and Controls and the primary calibrators and controls must be within  $\pm 1.5\%$ . The sponsor's studies show that the Architect Calibrators and Controls are stable for 12 months when stored at 2-8°C. Protocols and acceptance criteria for stability testing were described and found to be acceptable.

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.