

**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:

Product Code	Classification	Regulation Section	Panel
<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 $\mu\text{U/mL}$.

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 $\mu\text{U/mL}$.

J. Substantial Equivalence Information:**Calibrators**

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

Controls

Predicate	k030452
Describe the item being compared	
Bayer Ligand Plus 1, 2, 3 Controls	

Comparison with Predicate

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

Item	Control – Similarities	Predicate
Intended use	Verification of the accuracy and precision of quantitative assays	Same
Method	Chemiluminescent Microparticle Immunoassay (CMIA)	Same
Binding Protein	Insulin	Same
Levels	Three	Same
Item	Control – Differences	Predicate
Platform	Architect <i>i</i> System	ADVIA Centaur or ACS 180
Matrix	Liquid	Lyophilized
Type	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	http://www.fda.gov/cdrh/ode/99.html
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD	http://www.fda.gov/cdrh/ode/calibrator.html

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 1st 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.