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

A. 510(k) Number:
k082141

B. Purpose for Submission:
New Device

C. Measurand:
Calibrators and controls for C-peptide

D. Type of Test:
Calibrator and Control

E. Applicant:
Biokit S.A.

F. Proprietary and Established Names:
ARCHITECT C-Peptide Calibrators (model 3L53-01)
ARCHITECT C-Peptide Controls (model 3L53-10)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT (calibrator)	Class II	21 CFR§ 862.1150	Clinical Chemistry
JJX (control)	Class I, reserved	21 CFR§ 862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):
   See indications for use.

2. Indication(s) for use:
   Calibrators: The ARCHITECT C-Peptide Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of C-peptide in human serum, plasma and urine.

   Controls: The ARCHITECT C-Peptide Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of C-peptide in human serum, plasma and urine.

3. Special conditions for use statement(s):
   For *in vitro* diagnostic use.

4. Special instrument requirements:
   ARCHITECT *i* System

I. Device Description:

The ARCHITECT C-Peptide Calibrators and Controls are designed to be used in the ARCHITECT C-Peptide assay on the ARCHITECT *i* System.

Calibrators:

Calibrators A-F contain PBS buffer with heat inactivated horse serum and stabilizers. Calibrators B-F also contain human C-peptide (synthetic). Preservatives used are ProClin 300 and ProClin 950. Each ARCHITECT C-Peptide Calibrator kit contains 6 bottles of Calibrators (4.0 mL fill volume per bottle) with the following concentrations:
CAL A – 0.00 ng/mL, CAL B – 0.05 ng/mL, CAL C – 0.24 ng/mL, CAL D – 1.20 ng/mL, CAL E – 6 ng/mL, CAL F – 30 ng/mL

Controls:

The controls contain human C-peptide (synthetic) in PBS buffer with heat inactivated horse serum and stabilizers. Preservatives used are ProClin 300 and ProClin 950. Each ARCHITECT C-Peptide Control kit contains 3 bottles of Controls (8.0 mL fill volume per bottle) with the following concentrations:
Control Low – 1 ng/mL, Control Medium – 4 ng/mL, Control High – 16 ng/mL

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Calibrators: ADVIA Centaur and ACS:180 C-peptide Calibrator
   Controls: BAYER Ligand Plus 1,2,3 Controls
2. Predicate 510(k) number(s):
   Calibrators: k021532
   Controls: k030452
3. Comparison with predicate:

Calibrators (Similarities)		
Item	**Device**	**Predicate**
Intended use	The ARCHITECT C-Peptide Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of C-peptide in human serum, plasma and urine.	For in vitro diagnostic use in calibrating the ADVIA Centaur or ACS:180 C-peptide assays.
System Methodology	Chemiluminescent Microparticle Immunoassay (CMIA).	Two-site sandwich immunoassay using direct chemiluminescent technology.
Assay Protocols	Two-step immunoassay	Two-site sandwich immunoassay

Standardization	The ARCHITECT C-Peptide Calibrators are established against a set of internal Reference Calibrators, which are traceable to the WHO International Reference Reagent for C-peptide of human insulin for immunoassay, code 84/510, established 1986, from the National Institute for Biological Standards and Control (NIBSC).	The ADVIA Centaur C-peptide assay is standardized against World Health Organization (WHO) IS 84/510. Assigned values of calibrators are traceable to this standardization.
Calibrators (Differences)		
Item	**Device**	**Predicate**
Platform	ARCHITECT *i* System	Siemens Advia Centaur
Calibration Range/Levels	0.00 ng/mL (0 pmol/L) 0.05 ng/mL (17 pmol/L) 0.24 ng/mL (80 pmol/L) 1.20 ng/mL (400 pmol/L) 6.00 ng/mL (2000 pmol/L) 30.00 ng/mL (10000 pmol/L)	Low Calibrator High Calibrator
Matrix	PBS buffer with heat inactivated horse serum and stabilizers.	Citric acid buffer with casein and preservatives.

Controls (Similarities)		
Item	**Device**	**Predicate**
Intended use	The ARCHITECT C-Peptide Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of C-peptide in human serum, plasma and urine.	For in vitro diagnostic use to monitor the precision and the accuracy of immunochemistry test procedures for ADVIA Centaur®, ACS:180®, ADVIA IMS and ADVIA® Chemistry Systems.
System Methodology	Chemiluminescent Microparticle Immunoassay (CMIA).	Two-site sandwich immunoassay using direct chemiluminescent technology.
Assay Protocols	Two-step immunoassay	Two-site sandwich immunoassay
Controls (Differences)		
Item	**Device**	**Predicate**
Platform	ARCHITECT *i* System	Siemens ADVIA Centaur

Control Range/Levels	1.00 ng/mL (333 pmol/L) 4.00 ng/mL (1333 pmol/L) 16.00 ng/mL (5333 pmol/L)	Control 1 Control 2 Control 3
Matrix	PBS buffer with heat inactivated horse serum and stabilizers.	Prepared from Human serum. No preservatives or stabilizers added.

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

- OIVD: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

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:

Calibrators and controls are traceable to the WHO standard NIBSC code 84/510. The WHO standards are gravimetrically diluted to the target concentrations defined for the calibrators and controls to create reference materials. The reference materials are then used to standardize the consumer product.

Stability:

Freeze-thaw, open vial, and transport simulation studies were performed on the products. The stability protocols and acceptance criteria for these studies were reviewed and found to be acceptable. The ARCHITECT C-Peptide Calibrators and Controls are stable for 6 months when stored at 2-8^{o}C.

Value Assignment:

Values for the calibrators and controls are listed in section I. Calibrators and controls are verified using Relative Light Unit (RLU) comparison between target material and test material using the ARCHITECT *i* System. The consumer products are referenced to a secondary standard which is in turn referenced to the WHO standard mentioned above. Adjustments are performed if necessary so that the values of new calibrators are within the sponsor's manufacturing criteria when compared to the reference.

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.