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

A. 510(k) Number:

k060027

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Controls and Calibrators for dehydroepiandrosterone sulfate (DHEA-S) assay

D. Type of Test:

Not applicable. This submission is for clearance of **c**ontrols and calibrators.

E. Applicant:

BIOKIT S.A.

F. Proprietary and Established Names:

ARCHITECT DHEA-S CALIBRATORS (A-F) AND CONTROLS (LOW, MEDIUM AND HIGH)

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

Calibrators

The ARCHITECT® DHEA-S Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of DHEA-S in human serum and plasma.

Controls

The ARCHITECT® DHEA-S Controls are for the verification of the accuracy and precision of the ARCHITECT i System when used for the quantitative determination of DHEA-S in human serum and plasma.

2. Indication(s) for use:

Calibrators

The ARCHITECT® DHEA-S Calibrators are for the calibration of the ARCHITECT i System when used for the quantitative determination of DHEA-S in human serum and plasma.

Controls

The ARCHITECT® DHEA-S Controls are for the verification of the accuracy and precision of the ARCHITECT i System when used for the quantitative determination of DHEA-S in human serum and plasma.

3. Special conditions for use statement(s):

For Prescription use only.

4. Special instrument requirements:

The ARCHITECT® DHEA-S Calibrators and Controls are designed to be used for the calibration of the ARCHITECT® DHEA-S on the ARCHITECT® *i*2000 or *i*2000sr instrument platform. The instrument system was 510k cleared through submission number K983212.

I. Device Description:

Calibrator A contains human serum nonreactive for HBsAg, anti-HIV-1/HIV-2, HIV NAT, anti-HBc, HCV NAT, and anti-HCV. Calibrators B-F contain purified synthetic DHEA-S in human serum nonreactive for HBsAg, anti-HIV-1/HIV-2, HIV NAT, anti-HBc, HCV NAT, and anti-HCV. Preservative: Sodium azide. Each DHEA-S Calibrator kit contains 6 bottles of Calibrators (a 2.0 ml fill volume per bottle) with the following DHEA-S concentrations: 0, 5, 12, 60, 300, and 1500 µg/dL.

The controls contain purified synthetic DHEA-S in human serum nonreactive for HBsAg, anti-HIV-1/HIV-2, HIV NAT, anti-HBc, HCV NAT, and anti-HCV. Preservative: Sodium azide. Each DHEA-S control kit contains 3 bottles of controls (a 4.0 ml fill volume per bottle) with the following target concentrations (low, Medium, and High): 10, 100, and 1000 µg/dL.

J. Substantial Equivalence Information:

Predicate	**K935806**
Describe the item being compared	
DPC IMMULITE ® DHEA-SO4 Calibrators and Controls	

Similarities - Calibrators		
Item	Device	Predicate
Intended Use	The ARCHITECT® DHEA-S Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of DHEA -S in human serum and plasma.	DHEA-SO4 For the quantitative determination of dehydroepiandrosterone sulfate in serum.
System Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Chemiluminescent a solid phase enzyme immunoassay
Assay Protocols	Competitive assay	Competitive assay
Matrix	DHEA-S (synthetic) in human serum with preservative. (SodiumAzide)	Lyophilized DHEA -SO4 in human serum with preservative

Differences - Calibrators		
Item	Device	Predicate
Platform	ARCHITECT *i* System	Immulite 2000 Analyzer
Calibration Range/Levels	0, 5, 12, 60, 300, and 1500 µg/dL	15-1,000 µg/dL

Similarities - Controls		
Item	Device	Predicate
Intended Use	The ARCHITECT® DHEA-S Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of DHEA -S in human serum and plasma.	DHEA-SO4 For the quantitative determination of dehydroepiandrosterone sulfate in serum.
System Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Chemiluminescent a solid phase enzyme immunoassay
Assay Protocols	Competitive assay	Competitive assay
Matrix	DHEA-S (synthetic) in human serum with preservative. (SodiumAzide)	Lyophilized DHEA -SO4 in human serum with preservative

Differences - Controls		
Item	Device	Predicate
Platform	ARCHITECT *i* System	Immulite 2000 Analyzer
Matrix	Single constituent, DHEA -S (synthetic) in human serum with preservative. (Sodium Azide)	Multi constituent, Human serum based tri-level control containing over 25 constituents commonly measured by immunoassay.
Levels	10, 100, and 1000 µg/dL	Three levels, see package insert for measured values
Assay sample type	Serum and plasma	Serum

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

STANDARDS
Title and Reference Number
Interference Testing in Clinical Chemistry; Approved Guideline (CLSI EP 7-A)
Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (CLSI EP5-A)

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

L. Test Principle:

Not applicable. This submission is for calibrators and controls.

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):

Primary calibrators and controls are prepared gravimetrically by adding Synthetic DHEA-S obtained from a commercial source to a human serum-based matrix. The secondary calibrators and controls are also prepared gravimetrically by adding Synthetic DHEA-S obtained from a commercial source to a human serum-based matrix. Relative light unit (RLU) testing is performed and RLU values are compared to the corresponding Primary Calibrator or Control. The sponsor's acceptance criteria is that RLU variation must be within +/- 1.5%.

Target values for secondary calibrators are 0, 5, 12, 60, 300, and 1500 µg/dL DHEA-S. Target values for secondary controls are 10, 100, and 1000 µg/dL DHEA-S.

The DHEA-S Calibrators and Controls are stable for 6 months if stored at 2 to 8 ºC. 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.