JAN 26 2006

K060027

ARCHITECT ® DHEA-S 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordancewith the requirements of CFR

Preparation date: December 23 rd, 2005

Submitter Contact information:
Mr. Joan Guixer
Director of Quality Assurance and Regulatory Affairs
Biokit S.A.
Llica d'Amunt
Barcelona, Spain 08186

Device Name:

Calibrators
Classification Name: Calibrator, Secondary
Trade Name: ARCHITECT ® DHEA -S Calibrators (A-F)
Common name: Calibrator
Device Classification: 21 CFR 862.1150
Device Class: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls
Classification Name: Single (specified) analyte controls (assayed and unassayed)
Trade Name: ARCHITECT ® DHEA -S Controls (Low, Medium, and High)
Common name: Control
Device Classification: 21 CFR 862.1660
Device Class: Class I
Classification Panel: Clinical Chemistry
Product Code: JJX

Legally marketed device to which equivalency is claimed:

DPC IMMULITE ® DHEA -SO_4

Description of the Device:

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.

Comparison of Technological Characteristics:

Calibrators

Similarities:

Calibrator	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-SO_4 For the quantatitive 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-SO_4 in human serum with preservative

Controls

Similarities:

Controls	**Device**	**Predicate**
Intended Use	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	For the quantitative determination of dehydroepiandrosterone sulfate in serum intended strictly for in vitro diagnostic use.
Methodology	Chemiluminescent Microparticle Immunoassay (CMIA)	Chemiluminescence a solid phase enzyme immunoassay
Assay Protocol	Competitive assay	Competitive assay
Matrix	DHEA-S (synthetic) in human serum with preservative. (SodiumAzide)	Lyophilized DHEA-SO_4 in human serum with preservative

Calibrators

Differences:

Calibrators	Device	Predicate
Platform	ARCHITECT *i* System	Immulite 2000 Analyzer
Traceability	Sigma	Not in package insert
Standardization	Value assigned based on mass basis from a DHEA -S preparation (100% pure).	Not in package insert
Calibration Range/Levels	0, 5, 12, 60, 300, and 1500 µg/dL	15-1,000 µg/dL

Controls

Differences

Control	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.
Traceability	Sigma	Not in package insert
Value Assignment	Relative Light Units matched to secondary controls	Values derived from extensive analysis performed by DPC, and reflect instrument, reagent, and other within laboratory sources of variation.
Levels	10, 100, and 1000 µg/dL	Three levels, 2SD range 70-102, 222-288, 481-725 µg/dL [Example lot 020]
Assay Sample Type	Serum and plasma	Serum

Conclusion:

As summarized above the ARCHITECT® DHEA -S Calibrators (A-F) and Controls (Low, Medium, and High) are substantially equivalent to the DPC IMMULITE® DHEA -SO_4 Calibrators and Controls. Substantial equivalence for the calibrators has been demonstrated as recommended by the FDA guidance for Industry "Abbreviated 510(k) Submission for *In Vitro* Calibrators" (Issued on: Feb 22, 1999) and for controls as recommended by the FDA Guidance for Industry "Points to Consider Document on Assayed and Unassayed Quality Control Material" (Draft Guidance released for comment on Febuary 3, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 2006

Joan Guixer
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BioKit S.A.
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Spain 08186

Re: k060027
Trade/Device Name: ARCHITECT® DHEA-S CALIBRATORS (A-F) and
ARCHITECT® DHEA-S CONTROLS (LOW, MEDIUM, HIGH)
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class II
Product Code: JJX, JIT
Dated: December 27, 2005
Received: January 4, 2006

Dear Ms. Guixer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060027

Device Name: ARCHITECT ® DHEA-S CALIBRATORS (A-F) and ARCHITECT ® DHEA-S CONTROLS (LOW, MEDIUM, HIGH)

Indications 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

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.

For *in vitro* diagnostic use.

Prescription Use ____X___ **OR** (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chappie

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060027