510(k) SUMMARY

JUN 19 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: k063232

Preparation Date: October 17, 2006

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

Device Name:
Reagents
Classification Name: Parathyroid Hormone test system
Trade Name: ARCHITECT® iPTH Immunoassay
Common Name: iPTH test
Governing Regulation: 862.1545
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: CEW

Calibrators:
Classification Name: Calibrator, Secondary
Trade Name: ARCHITECT® iPTH Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls:
Classification Name: Single (specified) analyte controls (assayed and unassayed)
Trade Name: ARCHITECT® iPTH Controls
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Classification Panel: Clinical Chemistry
Product Code: JJX

Legally marketed device to which equivalency is claimed:
The ROCHE® Elecsys Parathyroid Hormone Test System (K992680) is used as the predicate device.

Intended Use of Device:

The ARCHITECT® Intact PTH assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of intact parathyroid hormone (PTH) in human serum and plasma on the ARCHITECT *i* System.

The ARCHITECT Intact PTH Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of intact PTH in human serum and plasma.

The ARCHITECT Intact PTH Controls are for the use in quality control to monitor the accuracy and precision of the ARCHITECT Intact PTH assay on the ARCHITECT *i* System for human serum and plasma.

Indications for use of the device:

The ARCHITECT Intact PTH assay as an aid in the differential diagnosis of hypercalcemia, hypocalcemia and parathyroid disorders.

Description of Device:

The ARCHITECT Intact PTH assay is a two-step sandwich immunoassay for the quantitative determination of intact PTH in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®. In the first step, sample, assay diluent, and anti-PTH coated paramagnetic microparticles are combined. Intact PTH present in the sample binds to anti-PTH coated microparticles. After washing, the anti-PTH acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of intact PTH in the sample and the RLUs detected by the ARCHITECT *i* System optics. The concentration of intact PTH in the sample is determined by comparing the chemiluminescent signal in the reaction to the ARCHITECT Intact PTH calibration.

Comparison of Technological Characteristics:

The ARCHITECT Intact PTH assay is a chemiluminescent microparticle immunoassay (CMIA) method for the quantitative determination of the intact PTH in human serum or plasma. The ROCHE Elecsys PTH assay uses streptavidin-coated microparticles for the determination of the routine intact PTH in human serum and plasma.

Summary of Non-Clinical Performance:

The ARCHITECT Intact PTH assay is substantially equivalent to the Roche Elecsys PTH.

The ARCHITECT Intact PTH demonstrated substantially equivalent performance to the Roche Elecsys PTH for the ROUTINE protocol with a correlation coefficient of 0.99 and for the STAT protocol with a correlation coefficient of 0.99.

Summary of Clinical Performance:

The ARCHITECT Intact PTH demonstrated substantially equivalent performance to the Roche Elecsys PTH with a correlation coefficient of 0.99.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

BioKit S.A.
c/o Mr. Joan Guixer
Quality Assurance and Regulatory Affairs
Can Male s/n
Llica dAmunt
Barcelona, Spain 08186

JUN 19 2007

Re: k063232
Trade/Device Name: Architect Intact PTH Reagents, Calibrators (A-F) and Controls (Low, Medium, High)
Regulation Number: 21 CFR §862.1545
Regulation Name: Parathyroid hormone test system.
Regulatory Class: Class II
Product Code: CEW, JJX, JIT
Dated: May 21, 2007
Received: May 24, 2007

Dear Mr. 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

ARCHITECT Intact PTH
ADMIN 5.0 Indications for Use Statement

510(k) Number (if known):

Device Name: ARCHITECT® Intact PTH REAGENTS, CALIBRATORS (A-F) and CONTROLS (LOW, MEDIUM, HIGH)

Indications for Use:
Reagents

The ARCHITECT Intact PTH assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of intact parathyroid hormone (PTH) in human serum and plasma on the ARCHITECT *i* System.

The ARCHITECT Intact PTH assay is intended to be used as an aid in the differential diagnosis of hpyercalcemia, hypocalcemia and parathyroid disorders.

Calibrators

The ARCHITECT Intact PTH Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of intact PTH in human serum and plasma.

Controls

The ARCHITECT Intact PTH Controls are for the use in quality control to monitor the accuracy and precision of the ARCHITECT Intact PTH assay on the ARCHITECT *i* System for human serum and plasma.

For *in vitro* diagnostic use.

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

Carol C. Benson

...n Sign-Off

...ice of In Vitro Diagnostic Device
...valuation and Safety

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