SEP - 3 2008

ARCHITECT C-Peptide

510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 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: k082141

Preparation Date: 25th July 2008

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

Device Name:

Calibrators:
Trade Name: ARCHITECT C-Peptide Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Chemistry
Product Code: JIT

Controls:
Trade Name: ARCHITECT C-Peptide Controls (Low, Medium and High)
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Classification Panel: Chemistry
Product Code: JJX

Legally marketed device to which equivalency is claimed:

Calibrators: ADVIA Centaur and ACS:180 C-peptide Calibrator (K021532)
Controls: BAYER Ligand Plus 1,2,3 Controls (K030452)

Intended Use of Device:

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.
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 3 2008

BioKit S.A.
Can Male S/N
c/o Mr. Joan Guixer
Quality Assurance and Regulatory Affairs Director
Llica D'Amunt
Barcelona, Spain 08186

Re: k082141
Trade Name: Architect C-Peptide Calibrators, and Architest C-Peptide Controls
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT, JJX
Dated: July 28, 2008
Received: July 30, 2008

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

Indication for Use

510(k) Number (if known): k082141

Device Name: ARCHITECT C-Peptide Calibrators (A – F) and ARCHITECT C-Peptide Controls (Low, Medium, and High).

Indication 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.

For *in vitro* diagnostic use.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k082141