AUG 16 2005

K050613

Section 3
Quantia Beta-2 Microglobulin
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Biokit S.A.
Can Male, Llissa d'Amunt
Barcelona
08186 Spain

Contact Person:

Contact: Joan Guixer, Quality Assurance and Regulatory Affairs Director
Phone: 34 - 93 860 90 00

Summary Prepared:

August 10th, 2005

Name of the device:

Quantia Beta-2 Microglobulin

Classification name(s):

866.5630	Beta-2-microglobulin immunological test system	Class II
JZG	System, Test, Beta-2-Microglobulin Immunological	

Identification of predicate device(s):

K943686 IL Test Beta-2-Microglobulin (Instrumentation Laboratory Co.)

Description of the device/intended use(s):

The Quantia Beta-2 Microglobulin is intended as a latex particle enhanced immunoturbidimetric assay for the *in vitro* quantitative determination of beta-2-microglubulin concentration in human serum or plasma (EDTA) on the AEROSET® instrument as an aid in the diagnosis of active rheumatoid arthritis and kidney disease.

Quantia PROTEINS Control is intended for use in monitoring the quality control of results obtained with the Quantia Beta-2 Microglobulin and Quantia A1-AT reagents by turbidimetry. (NOTE: This control has been also 510 (k) FDA submitted for use with Quantia A1-AT) For *in vitro* diagnostic use.

Quantia Beta-2 Microglobulin Standard is intended for use in establishing the calibration curve for the Quantia Beta-2 Microglobulin reagents by turbidimetry. For *in vitro* diagnostic use.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

Quantia Beta-2 Microglobulin is substantially equivalent to the commercially available predicate device, IL Test Beta-2-Microglobulin, in performance and intended use.

Summary of Performance Data:

In a method comparison study 105 serum samples with Beta-2 Microglobulin levels ranging from 1.01 to 101.1 mg/L were evaluated on the Abbott AEROSET® instrument. The slope was 0.876 and the correlation coefficient (r) was 0.9986 for the Quantia Beta-2 Microglobulin versus the predicate device.

Within run precision was assessed using the Quantia PROTEINS Controls I and II (low and high) and a third control spiked with pure Beta-2 Microglobulin at 10-15 mg/L, run in duplicate twice a day over twenty days (following the NCCLS EP5-A guideline), on the Abbott AEROSET® instrument. Control I gave a CV of 1.1 % (at a mean of 1.00 mg/L), Control II gave a CV of 0.9 % (at a mean of 5.46 mg/L) and the third control gave a CV of 0.9 % (at a mean of 13.61 mg/L). Total run precision gave a CV of 1.9% for Control I, 1.3% for Control II and 1.1% for the third control.

Linearity was assessed according to NCCLS EP6-A guideline. The assay was found to be linear within the following ranges:

0.25 to 16 mg/L without the automatic rerun capability.
0.02 to 100 mg/l with the automatic rerun capability.

The Limit of Quantification was defined as the minimum quantity of analyte that can be measured with a within-run CV below 20% and an error below ± 20 %. Without the automatic rerun capability, the Limit of Quantification for the Beta-2 Microglobulin assay is 0.25 mg/L and, with the automatic rerun capability, 0.02 mg/L.

The Interference study was assessed using the NCCLS guideline EP7-A. Interference testing is summarized as follows:

No significant interference from lipemia up to sample absorbance of 2.1 AU/cm at 660 nm.
No significant interference from triglycerides up to concentrations of 1300 mg/dL.
No significant interference from bilirubin up to concentrations of 20 mg/dL.
No significant interference from haemoglobin up to concentrations of 480 mg/dL.
RF interference is below 10% up to 288 IU/mL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2005

Biokit S.A.
c/o Ms Joan Guixer
Quality Assurance & Regulatory Affairs Director
Can Malé
Lliçà d'Amunt
Barcelona 08186, Spain

Re: k050613
Trade/Device Name: Quantia Beta-2 Microglobulin
Quantia Proteins Control
Quantia Beta-2 Microglobulin Standard
Regulation Number: 21 CFR 866.5630
Regulation Name: Beta-2-microglobulin Immunological Test System
Regulatory Class: Class II
Product Code: JZG, JJS, JJX
Dated: March 3, 2005
Received: March 10, 2005

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. 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/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
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): k050613

Device Name: Quantia Beta-2 Microglobulin

Indications for Use:

The Quantia Beta-2 Microglobulin is intended as a latex particle enhanced immunoturbidimetric assay for the *in vitro* quantitative determination of beta-2-microglubulin concentration in human serum or plasma (EDTA) on the AEROSET ® instrument as an aid in the diagnosis of active rheumatoid arthritis and kidney disease.

Quantia PROTEINS Control is intended for use in monitoring the quality control of results obtained with the Quantia Beta-2 Microglobulin and Quantia A1-AT reagents by turbidimetry. (NOTE: This control has been also 510(k) FDA submitted for use with A1-AT) For *in vitro* diagnostic use

Quantia Beta-2 Microglobulin Standard is intended for use in establishing the calibration curve for the Quantia Beta-2 Microglobulin reagents by turbidimetry. 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)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050613