K072078

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

Submitted by:

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DEC 1 9 2007

Contact Person:

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

Summary Prepared:

July 16, 2007

Name of the device:

Quantia Beta-2 Mcroglobulin

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.)

Quantia Beta-2-Microglobulin reagent was already 510(k) cleared as Quantia Beta-2-Microglobulin for its use with serum and EDTA plasma (K050613). A new submission for the Quantia Beta-2-Microglobulin reagent has been prepared as it is intended to also claim urine as a sample. The kit Quantia Beta-2-Microglobulin already cleared, contained Buffer and Latex Reagent. The Calibrators were already cleared in the submission K050613. There have also been added two different levels of controls in a separate kit. The controls are supplied by Bio-Rad (K851202/A1) and the values are assigned at Biokit S.A. This test with Biokit labeling was cleared k050596.

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, plasma (EDTA) or urine on the AEROSET ® Instrument as an aid in the diagnosis of active rheumatoid arthritis and kidney disease.

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 110 urine samples with Beta-2 Microglobulin levels ranging from 0.01 to 18.85 mg/L were evaluated on the Abbott AEROSET® instrument. The slope was 1.088, and the correlation coefficient (r) was 0.9894 for the Quantia Beta-2 Microglobulin versus the predicate device.

Within run precision assessed over multiple runs (with the Dilution Protocol 2) using urine samples on an AEROSET®, gave a CV of 4.2 % (at a mean of 0.066 mg/L), 1.7 % (at a mean of 0.094 mg/L), 1.5 % (at a mean of 0.204 mg/L) and 1.6 % (at a mean of 0.302 mg/L).

The linear range using urine samples is 0.025 to 1.6 mg/L with the automatic rerun capability (Dilution Protocol 2), 0.250 to 16 mg/L with Standard Dilution Protocol, and 16 to 96 mg/L with the automatic rerun capability Dilution Protocol 1.

There are no significant interferences in urine with this assay for conjugated bilirubin up to 20.9 mg/dL, high protein immunoglobulin (IgG) up to 100 mg/L and no positive or negative influence of the pH has been found. Ascorbic acid interference is below 10% up to 20 mg/dL. Do not use hemolyzed urine (hemoglobin interference is below 10% up to 23.6 mg/dL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 19 2007

Biokit S.A.
c/o Ms. Joan Guixer
QA & RA Director
Can Malé s/n
08186 Lliçà d'Amunt
Barcelona, Spain

Re: k072078
Trade/Device Name: Quantia Beta-2 Microglobulin
Regulation Number: 21 CFR 866.5630
Regulation Name: Beta-2-microglobulin immunological test system
Regulatory Class: Class II
Product Code: JZG
Dated: November 12, 2007
Received: November 14, 2007

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). 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
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

510(k) Number (if known): k072078

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-microglobulin concentration in human serum, plasma (EDTA) or urine on the AEROSET® Instrument as an aid in the diagnosis of active rheumatoid arthritis and kidney disease.

The Quantia Beta-2 Microglobulin is intended to be used with the already cleared Quantia PROTEINS Control (K050596) and the Beta-2 Microglobulin Standard (k050613).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072078