K050493

AUG 16 2005

Section 3
Quantia IgE
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:

June 29, 2005

Name of the device:

Quantia IgE

Classification name(s):

866.5510	Immunoglobulins A, G, M, D and E immunological test system	Class II
DGC	IgE, Antigen, Antiserum, Control	

Identification of predicate device(s):

K964152 UniCAP Total IgE Fluoroimmunoassay (Pharmacia)

Description of the device/intended use(s):

Quantia IgE is intended as a latex particle enhanced immunoturbidimetric assay for the *in vitro* quantitative determination of Immunoglobulin E concentration in human serum or plasma (EDTA, heparin, citrate) on the AEROSET System. Measurement of IgE is useful in the clinical diagnosis of IgE-mediated allergies, if used in conjunction with other clinical studies.

Quantia Ferritin / Myoglobin / IgE control is intended for use in monitoring the quality control of results obtained with the Quantia Ferritin, the Quantia Myoglobin and the Quantia IgE reagents by turbidimetry. (NOTE: These controls were previously FDA cleared for use with quantex Ferritin, reference K040879 and also cleared for use with quantex Myoglobin K042982) For *in vitro* diagnostic use.

Quantia IgE Standard is intended for use in establishing the calibration curve for the Quantia IgE reagents by turbidimetry. For *in vitro* diagnostic use.

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

Quantia IgE is substantially equivalent to the commercially available predicate device, UniCAP Total IgE Fluoroimmunoassay (Pharmacia), in performance and intended use.

Summary of Performance Data:

In a method comparison study evaluating 101 samples with IgE levels ranging from 10 to 2269 IU/mL on the Abbott AEROSET® instrument, the slope was 0.9650 and the correlation coefficient (r) was 0.9750 for Quantia IgE versus the UniCAP Total IgE Fluoroimmunoassay (K964152).

Within run precision assessed over multiple runs using Quantia Ferritin / Myoglobin / IgE Control on an Abbott AEROSET®, gave a CV of 6.4 % (at a mean of 47.3 IU/mL) and 0.7 % (at a mean of 406.5 IU/mL). A third control (control I + control II) gave a CV of 1.0 % (at a mean of 228.4 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
QA & RA Director
Can Malé
Lliçà d'Amunt
Barcelona, 08186 Spain

Re: k050493
Trade/Device Name: Quantia IgE
Quantia Ferritin/Myoglobin/IgE Control
Quantia IgE Standard
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A,G,M,D,E Immunological Test System
Regulatory Class: Class II
Product Code: DGC, JJX, JJS
Dated: February 24, 2005
Received: March 1, 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): K050493

Device Name: Quantia IgE.

Indications for Use:

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Quantia IgE Standard is intended for use in establishing the calibration curve for the Quantia IgE 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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050493