K050487

APR 26 2005

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Section 3
Quantia Lp(a)
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

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08186 Spain

Contact Person:

Contact: Joan Guixer, Quality Assurance and Regulatory Affairs Director

Phone: 34 - 93 860 90 00

Summary Prepared:

February 15, 2005

Name of the device:

Quantia Lp(a)

Classification name(s):

866.5600	Low-density lipoprotein immunological test system	Class II
DFC	lipoprotein, low-density, antigen, antiserum, control	

Identification of predicate device(s):

K013128 N-latex Lp(a) (Dade Behring)

Description of the device/intended use(s):

The Quantia Lp(a) is intended as a latex particle enhanced immunoturbidimetric assay for the *in vitro* quantitative determination of lipoprotein(a) [Lp(a)] concentration in human serum or plasma (EDTA, Heparin, Citrate) on the Clinical Chemistry Systems. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation.

Quantia Lp(a) Control is intended for use in monitoring the quality control of results obtained with the Quantia Lp(a) reagents by turbidimetry.

Quantia Lp(a) Standard is intended for use in establishing the calibration curve for the Quantia Lp(a) reagents by turbidimetry.

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

Quantia Lp(a) is substantially equivalent to the commercially available predicate device, N-latex Lp(a) (Dade Behring), in performance and intended use.

Summary of Performance Data:

In a method comparison study evaluating 104 samples with Lp(a) levels ranging from 2.4 to 188 mg/dL on the Abbott AEROSET® instrument, the slope was 1.121 and the correlation coefficient (r) was 0.9754 for Quantia Lp(a) versus the predicate device.

Within run precision was assessed over multiple runs using three different levels of control: (Quantia Lp(a) controls I and II and a mixture of control I and control II) on an Abbott AEROSET®. The precision assessed gave a CV of 2.3% (at a mean of 16.1 mg/dL) and 0.9% (at a mean of 57.9 mg/dL). The third control (control I + control II) gave a CV of 1.5 % (at a mean of 38.1 mg/dL).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 26 2005

Ms. Joan Guixer
Quality Assurance &Regulatory Affairs Director
Biokit S.A.
Can Male Llissa D'Amunt
Barcelona, Spain 08186

Re: k050487
Trade/Device Name: Quantia Lp(a)
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: DFC, JIS, JJX
Dated: February 22, 2005
Received: February 25, 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 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)276-0484. 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, 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

Indications for Use Statement

510(k) Number (if known): K050487

Device Name: Quantia Lp(a)

Indications for Use:

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Quantia Lp(a) standard is intended for use in establishing the calibration curve for the Quantia Lp(a) reagents by turbidimetry.

Prescription Use ✓ (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)
Division of Clinical Laboratory Devices
510(k) Number K050487