K103824

Date prepared **02 November 2010**

FEB 27 2012

510 (k) Summary- Human IgA Liquid Reagent Kit for use on the SPAPLUS

Introduction — According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Proprietary name: Human IgA Liquid Reagent Kit for use on the SPAPLUS
Classification name: IgA antigen, antiserum and control

Submitter — The Binding Site
P.O Box 11712
Birmingham B14 4ZB
Tel: +44 (0)121436 1000

Contact — Suzanne Horne

Device description: The Binding Site Human IgA Liquid Reagent Kit for use on the SPAPLUS is an immunoturbidimetric assy. Anti-IgA antibodies react with antigen in the sample to form antigen/antibody complex which is measured turbidimetrically.

Intended Use: The kit is intended for the quantitative *in vitro* determination of human IgA in serum, lithium heparin or EDTA plasma using the Binding Site SPAPLUS turbidimetric analyser.

Predicate device — We claim substantial equivalence to the Roche IgA Tina Quant Gen 2. on the Modular P(K040435) which measures low level IgA.

Similarities and differences to the predicate device

Topic	Predicate Device (K040435)	Modified Device
Intended Use	The kit is intended for the quantitative determination of human IgA in serum and plasma using a turbidimetric analyser.	Same
Method	Immunoturbidimetric assay	Same
Sample type	Serum Plasma - Heparin and EDTA	Same
Measuring range	0.05-45.0g/L (with extended rerun)	0.02-28g/L (with rerun at neat sample dilution)
Antigen excess	30g/L	40g/L

The fundamental scientific technology of the modified product is unchanged.

Modifications

- An additional low level range at a neat sample dilution (0.02- 0.7g/L) has been added to allow samples to be measured below 0.2g/L because the European Society for Immunodeficiencies (ESID) guidelines recommend that samples should be measured down to at least 0.07g/L in order to determine immunodeficiency. (ESID - European Society for Immunodeficiencies)
- The sample volume has changed from 25 µL to 8µL to allow the sample to be run at neat
- The antigen excess capacity of the kit has been improved to 40g/L.

The package insert has been updated to include the kit modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Binding Site
c/o Ms. Suzanne Horne
Regulatory Affairs
P.O. Box 11712
Birmingham, Westlands, B14 4ZB, UK

FEB 2 7 2012

Re: k103824
Trade/Device Name: Human IgA Liquid reagent kit for use on SPA_{Plus}^{TM}
Regulation Number: 21 CFR §866.5510
Regulation Name: Immunoglobulins A, G, M, D, E immunological test system
Regulatory Class: Class II
Product Code: CFN
Dated: December 10, 2011
Received: January 23, 2012

Dear Ms. Horne:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria Chan, 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): K103824

Device Name: Human IgA liquid reagent kit for use on the SPAPLUS

Indications for Use: This kit is intended for the quantitative *in vitro* determination of human IgA in serum, lithium heparin or EDTA plasma using the Binding Site SPAPLUS turbidimetric analyser. Measurement of IgA aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents. The test results are to be used in conjunction with other clinical and laboratory findings.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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) 103824