DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 14 2010

The Binding Site Group, Ltd
c/o Mr. Jay H. Geller
Authorized U.S. Representative
12100 Wilshire Boulevard, Suite 500
Los Angeles, CA 90025-7121

Re: k100588

Trade/Device Name: Human IgA1 Kit for use on SPAPLUS™
Human IgA2 Kit for use on SPAPLUS™
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: June 24, 2010
Received: June 29, 2009

Dear Mr. Geller:

This letter corrects our substantially equivalent letter of 8/16/2009.
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 (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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. 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

K100588

Indications for Use

AUG 16 2010

510(k) Number (if known): K100588

Device Name: Human IgA1 Kit for use on the SPAPlus™

Indications for Use: This kit is intended for quantifying IgA Subclass 1 (IgA1) in serum using The Binding Site SPAPlus turbidimetric analyser. Measurement of this immunoglobulin aids in the diagnosis of abnor
mal protein metabolism and the body's lack of ability to resist infectious agents. The test result is 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).

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K100588

K100588

Indications for Use

AUG 16 2010

510(k) Number (if known): k100588

Device Name: Human IgA2 Kit for use on the SPAPlus™

Indications for Use: This kit is intended for quantifying IgA Subclass 2 (IgA2) in serum using The Binding Site SPAPlus turbidimetric analyser. Measurement of this immunoglobulin aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents. The test result is 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) K100588