



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

The Binding Site Group, Ltd  
c/o Dr. Jill Constantine, Regulatory Affairs Scientist  
8 Calthorpe Road  
Edgbaston, Birmingham  
West Midlands, B15 1QT  
UK

April 15, 2013

Re: k122304  
Trade/Device Name: Human C1 Inactivator Kit for use on SPAPLUS  
Regulation Number: 21CFR§866.5250  
Regulation Name: Complement C1 inhibitor (inactivator) immunological test system  
Regulatory Class: Class II  
Product Codes: DBA  
Dated: March 28, 2013  
Received: April 03, 2013

Dear Dr. Constantine:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 -S**

Maria M. Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostics and Radiological

Health

Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if Known): k122304

**Device Name:** Human C1 Inactivator Kit for use on SPA<sub>PLUS</sub>

### Indications for Use:

This Human C1 Inactivator kit for use on SPA<sub>PLUS</sub> is intended for the in vitro measurement of human C1 inactivator in human serum using the SPA<sub>PLUS</sub> Analyzer. Measurement of C1 inactivator levels in serum is an aid in the diagnosis of hereditary angioedema (HAE) in conjunction with other laboratory and clinical 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 IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

**Maria M. Chan -S**

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Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k)  k122304