



OCT 15 2008

The Binding Site, Ltd.  
c/o Mr. Jay H. Geller  
East Tower, Suite 600  
2425 West Olympic  
Santa Monica, CA 90404

Re: k081674

Trade/Device Name: BINDAZYME™ Human Anti-Gliadin (MGP) IgG EIA Kit,  
BINDAZYME™ Human Anti-Gliadin (MGP) IgA EIA Kit,  
BINDAZYME™ Human Anti-Gliadin (MGP) EIA Kit (IgA or IgG)

Regulation Number: 21 CFR 866.5750

Regulation Name: Radioallergosorbent (RAST) immunological test system

Regulatory Class: Class II

Product Code: MST

Dated: October 7, 2008

Received: October 15, 2008

Dear Mr. Geller:

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.

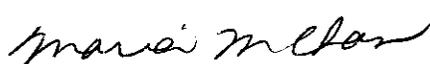
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Acting Division 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): K081674

Device Name: BINDAZYME™ Human Anti-Gliadin (MGP) IgG ELISA Assay  
BINDAZYME™ Human Anti-Gliadin (MGP) IgA ELISA Assay  
BINDAZYME™ Human Anti-Gliadin (MGP) EIA (IgG or IgA) Assay

Indications for Use: These assays are designed for the *in-vitro* measurement of specific IgG or IgA antibodies against a modified gliadin peptide (MGP) in human serum, as an aid in the diagnosis of coeliac disease in conjunction with other clinical and laboratory findings.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

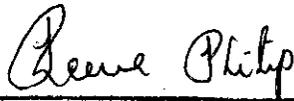
AND/OR

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 Device Evaluation (ODE)



Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k)   K081674