510(k) Summary

SEP - 7 2007

Submitted by:

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Contact Person: Dr. Jean Amiral, President & Scientific Director

Summary prepared by: April 30th 2007

Name of the Device: ZYMUTEST HIA IgG and ZYMUTEST HIA IgGAM

Classification Name: Anti-Platelet Factor IV Complex Antibodies

Regulation #: 864.7695

Product Code: LCO/0545

Identification of Predicate device:

1. ASSERACHROM ® HPIA Test Kit (Stago)
2. PF4 ENHANCED Solid Phase ELISA (GTI)

Predicate device 510 (k) number:

1. K003767
2. K053559

Description of the Device:

The ZYMUTEST HIA is solid phase enzyme linked immunosorbent assay (ELISA) designed to detect antibodies. These antibodies are found in some patients undergoing heparin therapy.

Indication for use:

ZYMUTEST HIA IgG and IgGAM kits are designed as a solid phase enzyme-linked immunosorbent assay (ELISA). These products are intended to be used as an in vitro diagnostics kit by Hematology, coagulation or other pathology laboratories to assist in screening patients samples for the presence of heparin-associated antibodies commonly found in patients with heparin induced thrombocytopenia or thrombosis (HIT).

Substantial equivalence is based on comparison of characteristics to the predicate devices.

ZYMUTEST HIA test kit uses the same principle as the predicate devices ASSERACHROM ®HPIA test kit and PF4 ENHANCED which are substantially equivalent in performance, intended use and technical principle.

Item	Device (ZYMUTEST HIA IgG and IgGAM)	Predicate (ASSERACHROM ®HPIA)	Predicate (PF4 Enhanced)
Intended Use	Determination of anti-heparin Platelet factor 4	Same	Same
Sample Requirement	Citrated human plasma or Serum	Same	Same
Design	Sandwich technique of enzyme-linked immunosorbent assay (ELISA)	Same	Same

In addition, these products have the same indication for use and same scientific technology.

Summary of performance Data:

Inter-lot reproducibility and comparison with predicate device

- Zymutest IgGAM was compared with Asserachrom (predicate device). Total of 44 plasma samples were analyzed. This was an internal study.

	Asserachrom	Zymutest IgGAM	%Agreement
Positive	28	30	93%
Negative	16	14	88%

- In clinical studies, Zymutest IgGAM was compared with Asserachrom for n=243 plasma samples.

Combined		Asserachrom	
Site 1 & 2		Positive	Negative
Zymutest IgGAM	Positive	48	32
	Negative	27	136
Agreement		76%	
Co-positivity		64%	
Co-negativity		81%	
Sample Size		243	

- In clinical studies, Zymutest IgGAM was compared with GTI PF4 Enhanced for n=345 plasma samples.

Combined Sites 1,2,3		GTI PF4-Enhanced	
		Positive	Negative
Zymutest IgGAM	Positive	101	17
	Negative	74	153
Agreement		74%	
Co-positivity		58%	
Co-negativity		90%	
Sample Size		345	

- In clinical studies, Zymutest IgG was compared with Seritonin Release Assay (SRA) for n=174 samples. Matches indicate that both were positive or both were negative.

# Matches	131
% Matching	75.29

- In clinical studies, Zymutest IgG was compared with Asserachrom for n=243 samples.

Combined Sites 1 & 2		Asserachrom	
		Positive	Negative
Zymutest IgG	Positive	33	17
	Negative	42	151
Agreement		76%	
Co-positivity		44%	
Co-negativity		90%	
Sample Size		243	

Reproducibility

Intra-assay: ZYMUTEST HIA Ig G and ZYMUTEST Ig GAM were tested on vials of positive control, in duplicate, taken at random from the lot.

Positive control	**N**	**Mean A450**	**CV%**
Anti PF4-IgG lot 061027D	6	1.31	3.07
Anti PF4 IgG lot 061214A	9	1.10	4.46
Anti PF4 IgGAM lot 061214D	9	1.74	4.75

The reproducibility for Intra assay precision for the positive control was performed. The CVs are below 10%, in compliance with the specifications, and confirm an excellent homogeneity for the intra assay.

Inter assay : Tested on one vial of positive control :

Positive control	N	Mean A450	CV%
Anti PF4-IgG lot 061027D	7	1.34	7.11
Anti PF4-IgGAM lot 061027G	7	1.84	7.50

The inter assay for all of the positive control results are in compliance with the specifications (CV below 10%).

Conclusion

Based on comparison with the legally marketed PF 4 Enhanced and Asserachrom devices, the data demonstrates that ZYMUTEST HIA Ig G and ZYMUTEST HIA Ig GAM devices perform as well as the predicate device and they do not present new issues of safety and effectiveness. The Intra and inter assay reproducibility of the devices (ZYMUTEST HIA Ig G and ZYMUTEST HIA Ig GAM) is within 10 % CV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Hyphen BioMed
C/O Ola Anderson
Aniara Corporation
6560 Gove Court
Mason, Ohio 45040

SEP - 7 2007

Re: k071255
Trade/Device Name: Zymutest HIA IgG and Zymutest HIA IgGAM
Regulation Number: 21 CFR 864.7695
Regulation Name: Platelet Factor 4 Radioimmunoassay
Regulatory Class: Class II
Product Code: LCO
Dated: April 30, 2007
Received: May 10, 2007

Dear Mr. Anderson:

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" (21CFR 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,

Robert L. Becker, M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number: **071255**

Device Name: **ZYMUTEST HIA IgG and IgGAM**

Indications for use:

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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

Office of In Vitro Diagnostic Device Evaluation and Safety

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