JAN 2 0 2006

K053559

510(k) Summary

I. Submitter:

Owner's Name:	GTI
Address:	20925 Crossroads Circle, Waukesha, WI 53186
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Name of Contact Person:	Leigh Ann Tidey
Date Summary Prepared:	December 9, 2005

II. Name of Device:

Device Name: PF4 ENHANCED®Solid Phase ELISA

Proprietary Name: PF4 ENHANCED® Solid Phase ELISA

Classification Name: Anti-Platelet Factor IV complex Antibodies,
Product Code: 0545

III. Name of predicate device for claiming equivalence

GTI-PF4 ELISA (K983379)

IV. Description of Device:

PF4 ENHANCED® Solid Phase ELISA microwells provide immobilized PF4:PVS complexes as a target for the detection of antibodies associated with Type II HIT which are found in some patients undergoing heparin therapy. The presence of these antibodies has been shown to be associated with heparin induced thrombocytopenia Type II (Type II HIT).

Patient serum is added to microwells coated with platelet factor 4 (PF4) complexed to polyvinyl sulfonate (PVS). If an antibody recognizing a site on PF4:PVS is present, binding will occur. Unbound antibodies are then washed away. An alkaline phosphatase labeled anti-human globulin reagent (Anti-IgG/A/M) is added to the wells and incubated. The unbound Anti-IgG/A/M is washed away and the substrate PNPP (p-nitrophenyl phosphate) is added. After a 30-minute incubation period, the reaction is stopped by addition of a sodium hydroxide solution. The optical density of the color that develops is measured in a spectrophotometer.

V. Intended Use

PF4 ENHANCED® is a qualitative solid phase enzyme linked immunosorbent assay (ELISA) designed to detect antibodies reactive with platelet factor 4 (PF4)

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when it is complexed to polyanionic compounds such as Polyvinyl Sulfonate (PVS). These antibodies are found in some patients undergoing heparin therapy.

VI. Support of substantial equivalence based on comparison of features, characteristics and components to the predicate device:

The characteristics of the two devices can be summarized as follows:

Features/Characteristics	PF4 ELISA Assay	PF4 ENHANCED®
Type of Test	Qualitative	Qualitative
Intended Use	PF4® ELISA Assay is a qualitative solid phase enzyme linked immunosorbent assay (ELISA) designed to detect antibodies reactive with platelet factor 4 (PF4) when it is complexed to polyanionic compounds such as Polyvinyl Sulfonate (PVS). These antibodies are found in some patients undergoing heparin therapy.	PF4 ENHANCED® is a qualitative solid phase enzyme linked immunosorbent assay (ELISA) designed to detect antibodies reactive with platelet factor 4 (PF4) when it is complexed to polyanionic compounds such as Polyvinyl Sulfonate (PVS). These antibodies are found in some patients undergoing heparin therapy.
Technology Used in Assay	ELISA	ELISA
Detection Method	Optical Density	Optical Density

In addition, these products have the same:

- indications for use
- performance characteristics
- assay protocol
- labeling (except for name)
- scientific technology

The differences between the two products are related to changes of materials within existing reagents:

1. A different wash buffer is used in PF4 Enhanced
2. A stabilizer was added to the storage buffer used in the alkaline phosphatase conjugated anti-IgG/A/M of PF4 Enhanced.

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Risk analysis did not identify any new issues of safety or effectiveness.

VII. Support of substantial equivalence with performance data:

The performance data used to validate the of the wash buffer change includes:

a) Data showing the effect of the material change on assay results using known patient samples.
b) Data showing the effect of the material change on kit stability (real time stability).

The performance data used to validate the stabilizer added to the storage buffer used in the alkaline phosphatase conjugated anti-IgG/A/M includes:

a) Data showing the effect of the material change on component stability (accelerated and real time stability studies on the alkaline phosphatase conjugated anti-IgG/A/M.)
b) Data showing the effect of the material change on kit stability (real time).
c) Data showing the effect of the material change on assay results using known patient samples.
d) Data showing the effect of the material change on assay reproducibility (within run precision, lot to lot reproducibility, and total reproducibility).
e) Data showing the effect of the material change on assay specificity (cross reactivity of other antibodies).

The details of each of these studies along with results and analysis can be found in Section 8: Performance Data Section.

Summary:

The data show that PF4 Enhanced is equivalent to PF4 ELISA.

VIII. Conclusion:

Based on comparison with the legally marketed PF4 ELISA, the data demonstrate that PF4 Enhanced ELISA performs as well as the predicate device and does not present new issues of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Leigh Ann Tidey, MS, MT(ASCP)SBB
Quality Assurance Manager
Genetic Testing Institute, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

JAN 2 0 2006

Re: k053559
Trade/Device Name: PF4 ENHANCED®
Regulation Number: 21 CFR § 864.7695
Regulation Name: Platelet factor 4 radioimmunoassay
Regulatory Class: II
Product Code: LCO
Dated: December 19, 2005
Received: December 21, 2005

Dear Ms. Tidey:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K053559

Device Name: PF4 ENHANCED®

Indications For Use:

GTI PF4 ENHANCED® is designed as a solid phase enzyme-linked immunosorbent assay (ELISA). The product is intended to be used as an in vitro diagnostics kit by hematology, coagulation or other pathology laboratories to assist in screening patient samples for the presence of heparin-associated antibodies commonly found in patients with heparin induced thrombocytopenia or thrombosis.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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