JAN 4 2006

Akers Biosciences
Accelerating Diagnostic Science To Deliver Real-Time Results

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K052697.

**807.92 (a)(1):**


**Name:** Akers Biosciences, Inc.
**Address:** 201 Grove Road
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**Contact:** Barbara A. Bagby


**807.92 (a)(2): Device Name – trade name and common name, and classification**

**Trade name:** Heparin/Platelet Factor 4 Antibody Serum Panel

**Common name:** Plasma, Coagulation Control

**Classification:** 21 CFR 864.5425
Product Code: GGN

**807.92 (a)(3): Identification of the legally marketed predicate device**

Heparin/Platelet Factor 4 Antibody Serum Panel is substantially equivalent to the controls provided in the GTI® PF4 ENHANCED® ELISA Assay manufactured by Genetic Testing Institute, Waukesha, WI; K983379

**807.92 (a)(4): Product Description**

The Heparin/Platelet Factor 4 Antibody Serum Panel is a well-qualified serum sample identified as a positive or negative sample against the PIFA® Heparin/Platelet Factor 4 Antibody Assay.

**Section 7, 510(k) Summary (continued)**

The panels are assembled from its repository of frozen serum samples, with reactivity as determined by the (FDA cleared) GTI® PF4 ENHANCED® ELISA Assay test currently available within the United States. No preservatives are added. Samples are chosen to provide a broad range of reactivity and to include samples with low antibody levels and samples with high antibody levels. A "positive" identified serum panel has OD values greater than 0.400 as determined on the GTI® PF4 ENHANCED® ELISA Assay test.

Two types of kit configurations are available, specifically for use on the PIFA ® Heparin/Platelet Factor 4 Antibody Assay test systems:

2 Member QC Panel
This panel consists of 1 positive and 1 negative sera each approximately 150 µl in total volume. These are normally used for routine quality checks and to help determine if technical errors or reagent failures have occurred.

Multi-Member Qualification Panel
This panel consists of either a 12-Member (10 positive and 2 negative sera) or 6-Member (5 positive and 1 negative sera). All panel member vials each contain approximately 150 µl in total volume. These are normally used for qualifying and evaluating PIFA® Heparin PF4 Antibody Assay test systems where a broad range of reactivity levels is desired. They provide comprehensive data for comparative analysis in regard to sensitivity, specificity, reproducibility, and lot-to-lot variability.

Data for comparative values on all panel members are available for reference only.

**807.92 (a)(5): Intended use**

The Heparin/Platelet Factor 4 Antibody Serum Panel is an assayed control, intended for use as a serum QC control to monitor and evaluate precision and accuracy of the (qualitative) PIFA® Heparin/PF4 Antibody Assay. Included are both confirmed positive and negative control panel members.

**Section 7, 510(k) Summary (continued)**

**807.92 (a)(5): Intended use (continued)**

The panel members enable the users to evaluate their PIFA® Heparin/PF4 Antibody Assay test systems and provide comprehensive data for comparative analysis.

**807.92 (a)(6): Technological Similarities and Differences to Predicate**

The following chart exhibits similarities and differences between the Heparin/Platelet Factor 4 Antibody Serum Panel (controls) and the controls provided with test GTI® PF4 ENHANCED® *ELISA distributed by Genetic Testing Institute* with their test.

| CHARACTERISTIC | Heparin/Platelet Factor 4 Antibody Serum Panel K040293 | GTI® PF4 ENHANCED® ELISA (controls provided with test) K983379 |
|---|---|---|
| Indications for Use | Assayed controls available for use as a QC panel for routine quality checks or as a qualification panel enabling users to evaluate their PIFA® Heparin PF4 Antibody Assay tests systems providing comprehensive data for comparative analysis. | Assayed controls included with each test. Run to help determine if technical errors or reagent failures have occurred. |
| Test which controls are used | Qualitative | Qualitative |
| Sample Matrix | Serum | Serum |
| Testing Environment | Professional | Professional |
| Positive Control Determination Level (OD reading) | ≥0.50 | ≥1.80 |
| Negative Control Determination Level (OD reading) | ≤0.32 | ≤0.30 |
| Test Determination for Positive | ≥0.40 | ≥0.40 |
| Test Determination for Negative | ≤0.40 | ≤0.40 |

The differences in the two testing platforms do not raise new issues of safety and effectiveness.

**Section 7, 510(k) Summary (continued)**

**807.92 (b)(1): Brief Description of Non-clinical data**

Studies were performed to evaluate the performance of the Heparin/Platelet Factor 4 Antibody Serum Panels for reproducibility (stability, including freeze-thaw), and precision.

Study #1 was performed to test the reproducibility of the Heparin/Platelet Factor 4 Antibody Serum Panel through repetition of the testing procedure utilizing the PIFA® Heparin/Platelet Factor 4 Rapid Assay in conjunction with the GTI® PF4 ENHANCED® ELISA Assay. This study also provided data supporting the ability of the Heparin/Platelet Factor 4 Antibody Serum Panel to remain stable after a number of freeze thaw cycles to mimic panel member handling conditions when utilized in the field. Included in the study were "borderline" samples that are near the cutoff range for positive and/or negative.

From testing each of the characterized samples in duplicate over a period of five days through a varying number of freeze-thaw cycles, the Heparin/Platelet Factor 4 Antibody Serum Panel consistently produced expected results from the PIFA® assay. In addition, the results consistently correlate with the O.D. values received when samples were run on the GTI® PF4 ENHANCED® ELISA assay, indicating the ability of the serum panel member to remain stable through numerous freeze-thaw cycles.

***Reproducibility***

| | | **GTI® PF4 ENHANCED® Value (pos/neg)** | |
|---|---|---|---|
| | | Positive | Negative |
| **PIFA® H/PF4 Rapid Assay** | Positive | 40 | 0 |
| | Negative | 0 | 20 |

Study #2 was conducted to support the quality of the serum panel members processed for use with the PIFA® Heparin/Platelet Factor 4 Rapid Assay. Included in the study were "borderline" samples that are near the cutoff range for positive and/or negative.

**Section 7, 510(k) Summary (continued)**

**807.92 (b)(1): Brief Description of Non-clinical data (continued)**

From testing each of the characterized samples in multiple format and consistently receiving the expected results from the PIFA® assay, the data reflects the precision provided by the assay. In addition, the results consistently correlate with the O.D. values received when samples were run on the GTI® PF4 ENHANCED® ELISA assay, illustrating the ability of the serum panel member to deliver appropriate results through multiple testing procedures.

***Precision***

| | | **GTI® PF4 ENHANCED® ELISA Assay Value (pos/neg)** | |
|---|---|---|---|
| | | Positive | Negative |
| **PIFA® H/PF4 Rapid Assay** | Positive | 30 | 0 |
| | Negative | 0 | 20 |

**807.92 (b)(2): Brief Description of Clinical Data**

Not applicable, all testing performed via bench by independent laboratory and/or internally.

**807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing**

The Heparin/Platelet Factor 4 Antibody Serum Panel values were evaluated for non-clinical and performance characteristics (precision and reproducibility) in comprehensive studies. These studies demonstrated that the test is safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Barbara A. Bagby
Director, Regulatory Affairs
Akers Biosciences, Inc.
201 Grove Road
Thorofare, NJ 08086

JAN 4 2006

Re: k052697
Trade/Device Name: Heparin/Platelet Factor 4 Antibody Serum Panel
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: November 23, 2005
Received: November 30, 2005

Dear Ms. Bagby:

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

Akers Biosciences, Inc.
Heparin/Platelet Factor 4 Antibody Serum Panel
510(k) Notification

# STATEMENT OF INTENDED USE

**510(k) Number (if Known):** K052697

**Device Name:** Heparin/Platelet Factor 4 Antibody Serum Panel

**Indications for Use:**

The Heparin/Platelet Factor 4 Antibody Serum Panel is an assayed control, intended for use as a serum QC control to monitor and evaluate precision and accuracy of the (qualitative) PIFA® Heparin PF4 Antibody Assay. Included are both confirmed positive and negative control panel members.

The panel members enable the users to evaluate their PIFA® Heparin PF4 Antibody Assay test systems and provide comprehensive data for comparative analysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CRF 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

Robert A. Becker
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052697