K970189 MAY 21 1997

AMERICAN BIOGENETIC SCIENCES, INC.

1539 North Ironwood Drive, South Bend, IN 46635 • Tel: (219) 271-3415 Fax: (219) 271-3423

Premarket Notification Summary

FiF™ Test

The ABS, Inc. FiF™ Test is an immunoprecipitation test indicated for the quantitative determination of fibrinogen in human plasma. The FiF™ test employs a monoclonal antibody (Mab), specific for intact (undegraded) plasma fibrinogen. When added to a plasma sample the FiF™ MAb precipitates the fibrinogen from solution.

The extent of the immunoprecipitate is determined by measuring the change in sample absorbance (at 340nm) after the addition of the FiF™ antibody. There is a linear correlation between the change in sample O.D. at 340nm and the concentration of fibrinogen in the solution. The test is calibrated using a standardized plasma sample provided with the kit.

The data and information in this submission demonstrate that American Biogenetic Sciences's FiF™ test is substantially equivalent to the Baxter Dade®, Data-Fi®, Fibrinogen determination kit. We believe that this product was available before May 28, 1976. The product insert for the predicate device has been included as Attachment B.

These two devices are similar in their intended use. Both make quantitative determination of fibrinogen in human plasma. Both employ standardized plasma controls for calibration. The Baxter Dade®, Data-Fi®, fibrinogen test is a functional test, measuring fibrinogen concentration as a function of the time it takes for a clot to form following the addition of excess thrombin to the test plasma sample.

The FiF™ test determines the level of fibrinogen by measuring the extent of immunoprecipitation when a fibrinogen specific antibody is added to the test plasma sample.

The Baxter functional assay maybe affected by the presence of anticoagulents such as heparin or by elevated levels of fibrinogen or fibrin degradation products. The ABS FiF™ test is not affected by anticoagulants or elevated fibrin/fibrinogen degradation products.

These differences are not considered significant and have no effect on the safety and effectiveness of the product.

A comparative study was performed on 101 plasma samples obtained (with patient consent.

The patient samples were collected from patients in the ER, Catherization Laboratory and also healthy volunteers. The samples were analysed at the same time using both the ABS FiF™ test and Baxter Dade's Data-Fi® functional test. There was a strong positive correlation R^2=0.83, (p=0.0001), demonstrating substantial equivalence of the two test systems. The performance of the FiF™ test was confirmed by linearity, precision and interference testing. The results are summarized below:

Linear Reportable Range:	50-1300mg/dL
Minimum Detectable Level:	59mg/dL
Interference:	The FiF™ test has been evaluated with a number of interfering substances. These interference studies utilized a dose response method with: Hemoglobin (100mg/dL) Direct bilirubin (16mg/dL) Total bilirubin (14mg/dL) Triglycerides (250mg/dL) Fibrinogen degradation (50mg/dL) Fibrin degradation products (50mg/dL) Heparin, EDTA and citrate as anticoagulants for sample collection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 21 1997

Ann D. McGonigle
Regulatory and Quality Assurance
American Biogenetic Sciences, Inc.
801 Albany Street, Suite 300
Boston, Massachusetts 02118

Re: K970189
FiF™ Test
Regulatory Class: II
Product Code: KQJ, GIS
Dated: March 31, 1997
Received: April 7, 1997

Dear Ms. McGonigle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

501 (k) Number (if known): K970189

Device Name: FIF™ Test

Indications For Use:

A fibrinogen determination test is indicated for testing of conditions in which blood coagulation is involved. Such conditions include disseminated intravascular coaagulation, cardiovascular disease and primary fibrinolysis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K970189

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)