K042687

DEC 1 0 2004

Summary of Safety and Effectiveness Information

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.

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	September 27, 2004

2. Name of Product: Enzygnost™ F1+2 (monoclonal)

3. FDA Classification Name: Fibrinogen/Fibrin degradation products assay

4. Predicate Device: Enzygnost™ F1+2 micro test kit (K922934)

5. Device Description: The Enzygnost™ F1+2 Test Kit is an enzyme immunoassay based on the sandwich principle in microtiter format utilizing monoclonal mouse antibodies. During the first incubation, the F1+2 antigen in the sample binds to F1+2 antibodies attached to the surface of the microtitration plate. After washing, peroxidase-conjugated antibodies to human prothrombin are bound to a free F1+2 determinant in a second reaction. The excess enzyme-conjugated antibodies are removed by washing; the bound enzyme activity is then determined. The enzymatic reaction between hydrogen peroxide and chromogen is terminated by the addition of dilute sulfuric acid. The color intensity, which is proportional to the concentration of F1+2, is determined photometrically and quantified by means of a calibration curve based on the standards included in the kit.

6. Intended Use: For the quantitative determination of the human prothrombin fragment F1+2 in plasma as an aid in diagnosing, monitoring and evaluating blood coagulation disorders involving changes in coagulation system activity.

7. Comparison to Predicate Device:

Conclusion: Split sample comparison between the Enzygnost™ F1+2 (monoclonal) and the Enzygnost™ F1+2 micro test kit (K922934) gave a correlation coefficient of 0.96, slope of 0.265, and an intercept of -29.378 when tested with 190 patient samples spanning the range of assay.

In a precision study using samples ranging from 38 - 646 pmol/L, the resulting coefficients of variation were 3.6%- 5.5% within run, and 4.4% - 11.2% day to day.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 0 2004

Ms. Donna A. Wolf
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k042687
Trade/Device Name: Enzygnost™ F1+2 (monoclonal)
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: MIF
Dated: November 17, 2004
Received: November 18, 2004

Dear Ms. Wolf:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
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 Statement

Device Name: Enzygnost™ F1+2 (monoclonal)

Indications for Use:

Enzygnost F1+2 (monoclonal) is an enzyme immunoassay for the quantitative determination of human prothrombin F1+2 in plasma. Measurement of F1+2 is used as an aid in the diagnosis, monitoring, and evaluation of acquired or hereditary blood coagulation disorders. It is indicated as an aid in assessing risk of thrombosis and in monitoring efficacy of anticoagulant therapy.

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

(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

510(k) K042687