AUG 1 1 2004

510(k) Summary for Advanced D-Dimer Assay

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: K041438

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

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 D-35001 Marburg, Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Kathleen Dray-Lyons Tel: 781-826-4551 Fax: 781-826-2497
Preparation date:	May 28, 2004

2. **Device Name/ Classification:** Advanced D-Dimer Assay
Class: Fibrinogen and Fibrin Split Product, Class II, 21 CFR 864.7320
Panel: Hematology (HE)
Product Code: DAP

3. **Identification of the Legally Marketed Device:**

Advanced D-Dimer Assay (K992957)

4. **Device Description:**

Polystyrene particles covalently linked to a monoclonal antibody (DD5) to the cross-linkage region of cross-linked fibrin degradation products (D-dimer) are agglutinated when mixed with samples containing D-dimer. The cross-linkage region has a stereosymmetrical structure, i.e. the epitope for the monoclonal antibody occurs twice. Consequently, one antibody suffices in order to trigger an agglutination reaction, which is then detected turbidimetrically via the increase in turbidity.

5. Device Intended Use:

Advanced D-Dimer is a latex-enhanced turbidimetric test for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human plasma for use with Dade Behring Coagulation Analyzers and Sysmex® Coagulation Systems. The Advanced D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

6. Medical device to which equivalence is claimed and comparison information:

The modified Advanced D-Dimer assay is substantially equivalent in intended use to the Advanced D-Dimer currently marketed (K992957). The modified Advanced D-Dimer assay, like the current Advanced D-Dimer assay, is intended for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human plasma for use with the Dade Behring Coagulation Analyzers Sysmex® Coagulation Systems.

7. Device Performance Characteristics:

Advanced D-Dimer Clinical Study Summary

Instrument	VTE Patients	Cut-off	Sensitivity (%)	Specificity (%)	NPV (%)
BCS® System	322	1.6	98	38	99
Sysmex® CA-1500	297	1.0	100	37	100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen A. Dray-Lyons
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714

AUG 11 2004

Re: k041438
Trade/Device Name: Advance D-Dimer Assay
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrinogen/Fibrin degradation products assay
Regulatory Class: II
Product Code: DAP
Dated: May 28, 2004
Received: June 2, 2004

Dear Ms. Dray-Lyons:

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

510(k) Number (if known): K041438

Device Name: Advanced D-Dimer

Indications For Use:

Advanced D-Dimer is a latex-enhanced turbidimetric test for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human plasma for use with Dade Behring Coagulation Analyzes and Sysmex® Coagulation Systems. The Advanced D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

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)

Maria Chan for
Josephine Bautista
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041438