

JAN 28 2000

K992957

**510(k) Summary for
Advanced D-Dimer**

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: _____

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: Rebecca S. Ayash
Tel: 302-631-6276

Preparation date: December 3, 1999

2. Device Name/ Classification:

Advanced D-Dimer: Fibrinogen/fibrin degradation products assay

Classification Number: Class II (864.7320)

3. Identification of the Legally Marketed Device:

Asserachrom[®] D-Di (K862156)

4. Device Description:

Polystyrene particles covalently linked to a monoclonal antibody (DD5) to the cross-linkage region of cross-linked fibrin degradation products containing 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.

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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 a Dade Behring Coagulation Analyzer.

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

There are a number of *in vitro* diagnostic products in commercial distribution, which employ immunoassay techniques for the quantitative measurement of cross-linked fibrin degradation products containing D-dimer in human plasma. One such product is the Asserachrom[®] D-Di (K862156). Advanced D-Dimer is substantially equivalent in intended use and results obtained to the Asserachrom[®] D-Di. The Advanced D-Dimer, like Asserachrom[®] D-Di is intended to be used for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in human plasma.

7. Device Performance Characteristics:

Correlation:

The Advanced D-Dimer assay was compared to the Asserachrom[®] D-Di by evaluating 316 samples ranging from 0.43 to 85.9 mg/l. A correlation coefficient of 0.91 was obtained, with a y-intercept value of 0.54 and a slope of 0.98.

Precision:

Precision studies were performed by the evaluation of two levels of control material and two levels of human plasma pools in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 0.8 to 3.8%, while the intra-assay precision ranged from 1.3 to 3.0%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 28 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rebecca S. Ayash
Manager, Regulatory Affairs, Biology
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: K992957
Trade Name: Advanced D-Dimer
Regulatory Class: II
Product Code: DAP
Dated: December 3, 1999
Received: December 6, 1999

Dear Ms. Ayash:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

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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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

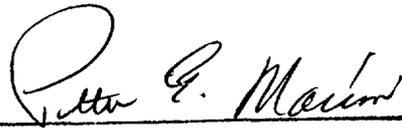
Enclosure

Indications Statement

Device Name: Advanced D-Dimer

Indications for Use:

Advanced D-Dimer is a latex-enhanced turbidimetric test for the quantitative measurement of cross-linked fibrin degradation products containing D-dimer in human plasma, and aids in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992957

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter-Use
(Optional Format 1-2-96)