K994341

MAR - 3 2000

510(k) Summary
for Fibrinogen Calibrator Kit

1. Manufacture'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 22, 1999

2. Device Name/ Classification:

Fibrinogen Calibrator Kit:	Fibrinogen Calibrators
Classification Number:	Class II (864.7340)

3. Identification of the Legally Marketed Device:

Dade Behring Fibrinogen Standards (K925988)

4. Device Description:
The Fibrinogen Calibrators are lyophilized calibrators prepared from pooled human plasma from selected, healthy donors, diluted with buffered solution or supplemented with purified fibrinogen and stabilized.

5. Device Intended Use:
Fibrinogen Calibrators 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss using Dade Behring Multifibrin U.

6. Medical device to which equivalence is claimed and comparison information:
There are a number of *in vitro* diagnostic products in commercial distribution, which are used for the establishment of reference curves. One such product is the Dade Behring Fibrinogen Standards (K925988). The Fibrinogen Calibrator Kit is substantially equivalent in intended use to the Fibrinogen Standards. The Fibrinogen Calibrator Kit, like the Fibrinogen Standards is intended to be used for the calibration of a fibrinogen assay

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR - 3 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K994341
Trade Name: Fibrinogen Calibrator Kit
Regulatory Class: II
Product Code: GFX
Dated: February 18, 2000
Received: February 24, 2000

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.

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,

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

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Indications for Use Statement

Device Name: Fibrinogen Calibrator Kit

Indications for Use:

Fibrinogen Calibrators 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss using Dade Behring Multifibrin U.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994341

(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)