K072304

510(k) Summary
Fibrinogen Calibrator Kit

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

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

SEP 19 2007

Contact Information: Dade Behring Inc.
Glasgow Site
Bldg. 500, M.S. 514
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Radames Riesgo
Tel: 305.480.7558

Preparation date: August 16, 2007

2. Device Name/ Classification:

Fibrinogen Calibrator Kit / Fibrinogen determination system, Class II (864.7340)

3. Identification of the Legally Marketed Device:

Fibrinogen Calibrator Kit (K994341)

4. Device Description:

The Fibrinogen Calibrators are lyophilized calibrators prepared using pooled human plasma from selected, healthy donors that has been diluted with buffer 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 Multifibren™ U.

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

The modified Fibrinogen Calibrator Kit is substantially equivalent in intended use and performance to the Fibrinogen Calibrator Kit (K994341) currently marketed. Both devices are intended for use as calibrators for fibrinogen determination using the Dade Behring Multifibren™ U assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Radames Riesgo
Regulatory Affairs & Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Building 500 MS 514
Newark, Delaware 19714

SEP 19 2007

Re: k072304
Trade/Device Name: Fibrinogen Calibrator Kit
Regulation Number: 21 CFR 864.7340
Regulation Name: Fibrinogen determination system
Regulatory Class: Class II
Product Code: GFX
Dated: August 16, 2007
Received: August 17, 2007

Dear Mr. Riesgo:

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072304

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 Multifibren™ U.

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) K072304