JUN 2 9 2005

# 510(k) Summary for Dade® Thrombin Reagent

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: K050928

**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: June 24, 2005

**2. Device Name** Dade® Thrombin Reagent and Dade® Owren's Veronal Buffer

**Classification:** Fibrinogen Determination System, Class II, 21 CFR 864.7340

**Panel:** Hematology

**Product Code:** KQJ

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

Dade® Fibrinogen Determination Reagents kit (Pre-1976) and
Dade® Thrombin Reagent (BK860038)

**4. Device Description:**

Fibrinogen is a plasma protein which is converted from a soluble protein to an insoluble polymer by the action of thrombin resulting in the formation of a fibrin clot. The thrombin clotting time of dilute plasma is inversely proportional to the fibrinogen concentration of the plasma. Using this principle, Clauss developed a simple quantitative assay for fibrinogen by measuring the clotting time of dilute plasma when excess thrombin is added. The clotting time obtained is then compared with that of a standardized fibrinogen preparation.

## 5. Device Intended Use:

For use in the quantitative determination of fibrinogen in plasma and to accelerate coagulation of anticoagulated samples for immunohematology.

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

The modified Dade® Thrombin Reagent is substantially equivalent to the currently marketed Dade® Fibrinogen Determination Reagents kit (Pre-1976) and Dade® Thrombin Reagent (BK860038). The modified Dade® Thrombin Reagent, like the current Dade® Fibrinogen Determination Reagents kit is intended for use in the quantitative determination of fibrinogen in human plasma and to accelerate coagulation of anticoagulated samples for immunohematological studies.

## 7. Device Performance Characteristics:

**Method Comparison Study**
**Dade® Fibrinogen Determination Reagents vs. Dade® Thrombin Reagent**

| Dade® Thrombin Reagent | (n=) | Slope | Intercept | Correlation Coefficient |
|---|---|---|---|---|
| **SHP Lot # 502587** | 80 | 1.03 | -0.063 | 0.995 |
| **SHP Lot # 502589** | 80 | 0.946 | -0.027 | 0.993 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 9 2005

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

Re: k050928
Trade/Device Name: Dade® Thrombin Reagent
Regulation Number: 21 CFR § 864.7340
Regulation Name: System, Fibrinogen Determination
Regulatory Class: II
Product Code: KQJ
Dated: April 13, 2005
Received: April 14, 2005

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

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

Enclosure

## Indications Statement

K050928

**Device Name:** **Dade® Thrombin Reagent**

**Indications for Use:**
For use in the quantitative determination of fibrinogen in plasma and to accelerate coagulation of anticoagulated samples for immunohematology studies.

Prescription Use ✓
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____
(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) K050928