JUL 22 1998

K974343

510(k) Summary of Safety and Effectiveness
Dade® Innovin®
November 18, 1997

Dade International Inc.
2173 NW 99th Avenue
Miami, FL 33172
Contact Person: Radames Riesgo at 305-392-5615 or by facsimile at 305-392-5622.

Trade or Proprietary Name: Dade® Innovin®

Common or Usual Name: Prothrombin time assay

Classification Name: Prothrombin Time Test (21 CFR § 864.7750)

Registration Number:

Dade International Inc. 1851 Delaware Pkwy. Miami, FL 33125	1017272
Dade International Inc. 2173 NW 99th Avenue Miami, FL 33172	1025506

The product is an *in vitro* diagnostic test for the determination of prothrombin time and prothrombin time-based assays. Dade® Innovin® is a lyophilized preparation of purified recombinant human tissue factor produced in *E. coli* combined with synthetic phospholipids, calcium and stabilizers. The reagent initiates clotting via the extrinsic common pathway in a global screening test, the prothrombin time (PT). The obtained clotting time detects single or combined deficiencies of the extrinsic coagulation system indicative of hereditary and acquired coagulation disorders, is a sensitive monitoring test for oral anticoagulation therapy and an assay for specific coagulation factors.

Dade® Innovin® is substantially equivalent in intended use and performance to Dade® Thromboplastin IS (K891169). Both the proposed product and the predicate device are formulated to provide high sensitivity to factor deficiencies and can be used for monitoring patients on oral anticoagulants. In a comparative performance study, specimens were tested using both reagents. The correlation coefficient in PT seconds between the two products was 0.975 and the regression equation was $Y = 1.32X - 8.3$. When results were converted into INR (International Normalized Ratio) values, the correlation coefficient was 0.98 and the regression equation was $Y = 0.99X - 0.09$.

We believe the documentation included in this premarket notification demonstrates that Dade® Innovin® reagent is substantially equivalent to Dade® Thromboplastin IS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1998

Radames Riesgo
Manager Regulatory Affairs
DADE Behring Inc.
P.O. Box 520672
Miami, Florida 33152-0672

Re: K974343
Dade® Innovin®
Regulatory Class: II
Product Code: GJS
Dated: July 1, 1998
Received: July 2, 1998

Dear Mr. Riesgo:

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 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 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/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

510(k) Number (if known): _____

Device Name: DADE® INNOVIN ®

Indications For Use:

For use in prothrombin time determinations and prothrombin time-based assays.

(PLEASE DO NOT WITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974343