

OCT 13 1998

2981709

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21CFR 807.92.

Coagulation Factor V Deficient Plasma

Summary of Safety and Effectiveness

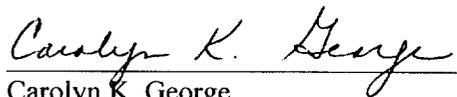
Coagulation Factor V Deficient Plasma is a Class II device and has a classification name of coagulation factor deficient plasma (21 CFR 864.7290). It is intended as an *in vitro* reagent for the determination of the activity of coagulation factor V, as indicated for the diagnosis of congenital or acquired Factor V deficiency states. When used with the Dade Behring ProC APC assay, the factor V deficient plasma is suitable for detecting Factor V Leiden mutation.

Coagulation Factor V Deficient Plasma is a lyophilized human plasma with a residual Factor V activity of less than or equal to 1% and contains activities of the remaining coagulation factors of more than 40%. This composition is similar to the Chromogenix V-Def Plasma, the predicate device, which consists of lyophilized human plasma deficient in Factor V. In addition, both deficient plasmas contain a heparin antagonist. When both reagents are used with an appropriate APC Resistance assay, highly sensitive determination of the Factor V Leiden mutation is possible.

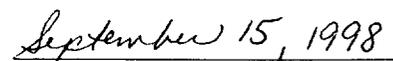
Comparative Analysis: In a study of 300 patient samples (88 Factor V Leiden + 212 healthy blood donors), Coagulation Factor V Deficient Plasma used with the Dade Behring ProC APC assay yielded a specificity of 100% and a sensitivity of 99% for Factor V Leiden. In comparison, the Coatest APC Resistance VS assay (used with the V-Def Plasma) yielded a specificity of 99% and a sensitivity of 100% for Factor V Leiden.

Precision: A reproducibility study for Factor V was run on the Behring Coagulation Timer with samples in both normal and pathological ranges. Samples were run over a five day period with one run per day in replicates of eight. Precision data were calculated in a manner consistent with NCCLS Guideline EP5. The reproducibility study resulted in a 2.3% CV for the normal sample and 4.9% CV for the pathological sample.

Dade Behring considers the Coagulation Factor V Deficient Plasma to be substantially equivalent to the Chromogenix V-Def Plasma in terms of intended use, reagent composition and overall performance characteristics. When used with the Dade Behring ProC APC assay, sensitive determination of Factor V Leiden is possible.



Carolyn K. George
Manager, Regulatory Affairs, Biology



Date

510K
Summary
(Revised)



OCT 13 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carolyn K. George
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K981709
Coagulation Factor V Deficient Plasma
Regulatory Class: II
Product Code: GJT
Dated: September 15, 1998
Received: September 16, 1998

Dear Ms. George:

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.

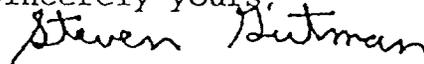
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

*Ravi
Ind. -
Use*

Indications Statement

Device Name: Dade Behring Coagulation Factor V Deficient Plasma

Indications for Use: *In vitro* diagnostic reagent for the determination of the activity of coagulation factor V and for the detection of Factor V Leiden in citrated human plasma when used in conjunction with the Dade Behring ProC APC Method.

Carolyn K. George

Carolyn K. George
Manger, Regulatory Affairs

September 15, 1998

Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maini

Division Sign-Off
Division of Clinical Laboratory Devices
510(k) Number *K981709*

510(k) Number

Division Sign-Off
Office of Device Evaluation

prescription use

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