

AUG 27 2002

K022290

### Summary of Safety and Effectiveness Information

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.

**Submitter's Name:** Donna A. Wolf  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714-6101

**Date of Preparation:** August 7, 2002

**Name of Product:** Protein S Ac

**FDA Classification Name:** Factor Deficiency Test

**Predicate Device:** STA® StaClot® Protein S kit (K913424)

#### Device Description:

Protein S Ac is a reagent intended for the quantitative determination of the functional activity of protein S in human plasma.

Protein Ca proteolytically cleaves F Va which is generated during the activation of the coagulation cascade by RVV (venom of *Vipera russelli*). In this reaction protein S acts as a cofactor which accelerates the reaction. As a result, the coagulation time increases proportionally to the activity of protein S in the sample. The addition of deficient plasma ensures that the test mixture has a sufficient supply of fibrinogen, Factor V and the other necessary coagulation factors.

Coagulation is triggered at the level of Factor X by the FX activator of RVV. FXa forms thrombin from prothrombin under the action of the remaining Factor Va. The resulting thrombin finally converts fibrinogen to fibrin.

**Intended Use:** For the quantitative determination of the functional activity of protein S in human plasma.

#### Comparison to Predicate Device:

##### Conclusion:

Split sample comparison between the Protein S Ac and the STA® StaClot® Protein S kit (K913424) gave a correlation coefficient of 0.919, slope of 0.961, and an intercept of +1.534 when tested with 239 patient samples spanning the range of the target population.

For normal plasma samples measured using the Sysmex® CA 1500, the resulting variation coefficients ranged between 3.6% and 5.1% within the series of measurements, and between 2.0% and 4.1% from day to day. Total precision ranged from 4.6 to 5.5%. For pathologically deficient plasma samples which were measured using the Sysmex® CA 1500, the resulting variation coefficients ranged between 4.7% and 9.2% within the series of measurements, and between 1.9% and 7.7% from day to day. Total precision ranged from 4.8 to 11.6%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**AUG 27 2002**

Ms. Donna Wolf  
Senior Regulatory Affairs Specialist  
Dade Behring, Inc.  
514 GBC Drive  
Newark, Delaware 19702

Re: k022290  
Trade/Device Name: Protein S Ac  
Regulation Number: 21 CFR § 864.7290  
Regulation Name: Factor Deficiency Test  
Regulatory Class: II  
Product Code: GGP  
Dated: July 12, 2002  
Received: July 13, 2002

Dear Ms. Wolf:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

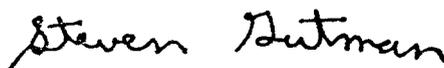
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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

### Indications For Use Statement

**Device Name:** Protein S Ac

**Indications for Use:**

Reagent for the quantitative determination of the functional activity of protein S in human plasma.



(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K 022290

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the-counter Use \_\_\_\_\_

(Optional format 1-2-96)