

K 970645

MAY 19 1997



**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For BC Thrombin Reagent**

1. Manufacturer and Contact Information:

Manufacturer: Behring Diagnostics GmbH
P.O. Box 1149
35001 Marburg, Germany

Contact Information: Paul Rogers
Behring Diagnostics Inc.
3403 Yerba Buena Road
P.O. Box 49013
San Jose, CA 95161-9013
Tel: 408-239-2000

2. Device Classification Name:

The BC Thrombin Reagent is a Class II device and has a classification name of thrombin time test (21 CFR §864.7875).

3. Intended Use:

BC Thrombin Reagent is intended for the determination of the thrombin time in human plasma.

4. Device Description and Characteristics:

The BC Thrombin Reagent consists of lyophilized bovine thrombin and bovine albumin, and buffer solution (HEPES). This is similar to the Behring Test Thrombin Reagent, the predicate device, which consists of lyophilized bovine thrombin and bovine albumin, and HEPES buffer solution.

Comparative Analysis: A total of 67 patients (normal blood donors, patients undergoing heparin therapy, patients with increased fibrin degradation products) were tested with the BC Thrombin Reagent and compared with the predicate device. Regression analysis of the test results gave a correlation coefficient of 0.93, a slope of 1.48, and a y-intercept of -5.5.

Precision: Precision studies were performed following the NCCLS EP5 guideline using three plasma samples (two in the normal range and one in the pathological range). The within-run precision ranged from 2.2% to 6.2%. The total precision ranged from 3.8 to 7.4%.

5. Substantial Equivalence:

Behring Diagnostics Inc. considers the BC Thrombin Reagent to be substantially equivalent to the Behring Test Thrombin Reagent in terms of intended use, reagent composition, and overall performance characteristics.

510(k) Number (if known):

Device Name: BC Thrombin Reagent

Indications For Use:

The BC Thrombin Reagent is used for the determination of the thrombin time in human plasma. The determination of thrombin time is important in:

- The monitoring of heparin therapy.
- The monitoring of fibrinolysis therapy.
- The screening of disorders of fibrin formation.
- The differentiating between a heparin-induced prolongation of the thrombin time and fibrin formation disorders.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division of) **Medical Devices**
Division of **Medical Devices**
510(k) Number K 970645

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 19 1997

Paul L. Rogers, Jr.
• Senior Manager of Regulatory Affairs
Behring Diagnostics
P.O. Box 49013
San Jose, California 95161-9013

Re: K970645
BC Thrombin Reagent
Regulatory Class: II
Product Code: GJA
Dated: April 9, 1997
Received: April 10, 1997

Dear Mr. Rogers:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

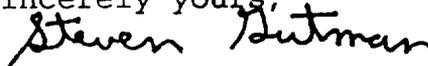
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known):

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