

JAN 11 2000

510(k) Summary for Behring Coagulation System

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: K992959

1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
Marburg/Germany

Contact Information: Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714
Attn: Rebecca S. Ayash

Preparation date: August 31, 1999

2. Device Name/ Classification:

Behring Coagulation System: Multipurpose system for *in vitro*
Coagulation studies

Classification Number: Class II (864.5425)

3. Identification of the Legally Marketed Device:

Bio-Tek EL309 microplate reader (K842085)

4. Device Description:

The current BCS was determined to be substantially equivalent as a fully automated photometric coagulation analyzer in 510(k) notification K970431. The current BCS was cleared to perform coagulometric and chromogenic tests, such as the routine tests prothrombin time, partial thromboplastin time, and fibrinogen, as well as the special tests, single factor determination antithrombin IIIa, protein C and plasminogen. The modified BCS has the ability to perform coagulometric, chromogenic and immunochemical assays (e.g., latex enhanced turbidimetric test Advanced D-Dimer). The addition of the immunochemical measuring method is the subject of this modification.

5. Device Intended Use:

The Behring Coagulation System performs quantitative assays of specific parameters in human citrated plasma.

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

There are a number of photometric analyzers for the measurement of immunochemical assays. One such product is the Bio-Tek EL309 microplate reader. This instrument is a photometric analyzer for measuring immuno complexes. The BCS is substantially equivalent in intended use and results obtained to the Bio-Tek EL309 microplate reader, which was the subject of 510(k) K842085. Both instruments use photometric technology at various wavelengths for the measurement of immuno complexes.

7. Device Performance Characteristics:

Correlation:

The Advanced D-Dimer assay was compared to the Asserachrom[®] D-Di by evaluating 316 samples ranging from 0.43 to 85.9 mg/l. A correlation coefficient of 0.91 was obtained, with a y-intercept value of 0.54 and a slope of 0.98.

Precision:

Precision studies were performed by the evaluation of two levels of control material and two levels of human plasma pools in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 0.8 to 3.8%, while the intra-assay precision ranged from 1.3 to 3.0%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 11 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rebecca S. Ayash
Manager, Regulatory Affairs, Biology
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K992959
Trade Name: Behring Coagulation System
Regulatory Class: II
Product Code: JPA
Dated: December 6, 1999
Received: December 7, 1999

Dear Ms. Ayash:

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 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). 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.

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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/dsma/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

Dade Behring Inc.
Behring Coagulation System
Additional Information
510(k) - K992959

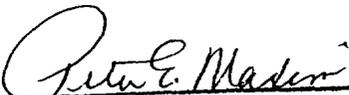
Indications Statement

Device Name: Behring Coagulation System

Indications for Use:

The Behring Coagulation System (BCS) is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Antithrombin IIIa
- Batroxibin
- D-dimer
- Deficient Plasmas
- Fibrinogen
- Heparin
- Plasminogen
- Protein C-clotting
- Protein C-chromogenic
- Thrombin Time
- Von Willebrand factor



 (Division Sign-Off)
 Division of Clinical Laboratory Devices K992959
 510(k) Number _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter-Use
(Optional Format 1-2-96)