AUG - 9 2001

510(k) Summary for BCT™ 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: K011665

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:	May 29, 2001

2. Device Name/ Classification:

BCT™ System:	Multipurpose system for *in vitro* Coagulation studies
Classification Number:	Class II (864.5425)

3. Identification of the Legally Marketed Device:

BCT™ System [K955278, K001064, K001067]

4. Device Description:

The current BCT™ System was originally determined to be substantially equivalent as a fully automated photometric coagulation analyzer in 510(k) Premarket Notification K955278. Subsequent to its clearance, the indications for use of the instrument were modified under in 510(k) Premarket Notifications, K001064 and K001067 for the addition of various analytes. The current BCT™ System was cleared to perform coagulometric, chromogenic, and immunochemical tests, such as the routine tests: prothrombin time, partial thromboplastin time, heparin, and fibrinogen, as well as the special tests: single factor determination, antithrombin IIIa, batroxobin, plasminogen, protein C, and D-dimer. The inclusion of the new testing parameter, lupus anticoagulants (LA), is the subject of this modification. The addition of the new proposed analyte to the instrument was accomplished without modification to the instrument principle, operation, hardware or instruction manual.

5. **Device Intended Use:**
The Behring Coagulation Timer Analyzer (BCT™) System is an automated blood plasma coagulation analyzer for *in vitro* diagnostic use.

6. **Medical device to which equivalence is claimed and comparison information:**
The BCT™ System is substantially equivalent in intended use and results obtained to the Sysmex® CA-6000 System, which was the subject of 510(k) K964139. Both instruments use light at various wavelengths for the measurement of several coagulation assays.

7. **Device Performance Characteristics:**

Correlation:
The modified BCT™ System comparison study evaluated plasma samples on the BCT™ System with Dade Behring LA 1 and LA 2 Reagents versus Dade Behring LA 1 and LA 2 Reagents on the Sysmex® CA-6000 System.

BCT™ System vs. Sysmex® CA-6000 System Method Comparison Summary

Assay	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
LA 1 Screening Reagent (seconds)	207	0.968	y=0.87x + 4.34
LA 2 Confirmation Reagent (seconds)	208	0.882	y=0.76x + 5.46
LA 1/LA 2 Ratio	206	0.965	y=1.08x + 0.05
LA 1 Screening Reagent (normalized)	207	0.969	y=0.89x + 0.11
LA 2 Confirmation Reagent (normalized)	208	0.882	y=0.84x + 0.15
LA 1/LA 2 Ratio (normalized)	206	0.964	y=0.97x + 0.04

Precision:
Precision studies were performed by the evaluation of three levels of control material in a manner consistent with NCCLS Guideline EP5-A.

Summary of Precision Studies

Assay	Sample	Total Mean	Run-to-Run (%CV)	Within-Run (%CV)	Total (%CV)
LA 1 Screening Reagent (seconds)	LA Control High	71.92	1.6	1.3	2.0
	LA Control Low	51.23	1.7	1.4	2.2
	Control Plasma N	34.85	0.9	0.6	1.0
LA 2 Confirmation Reagent (seconds)	LA Control High	37.80	1.0	0.5	1.1
	LA Control Low	35.42	1.4	0.9	1.6
	Control Plasma N	36.59	1.7	0.8	1.9
LA 1/LA 2 Ratio	LA Control High	1.90	0.9	1.2	1.4
	LA Control Low	1.45	1.1	0.7	1.3
	Control Plasma N	0.95	0.9	0.9	1.2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rebecca S. Ayash
Director, Regulatory Affairs
DADE BEHRING, INC.
P.O. Box 6101
Newark, Delaware 19714

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Re: K011665
Trade Name: BCT™ System
Regulation Number: 21 CFR § 864.5425
Regulatory Class: II
Product Code: JPA
Dated: May 29, 2001
Received: May 30, 2001

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.

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,

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

Indications Statement

Device Name: BCT™ System

Indications for Use:

The BCT™ System is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

- Activated Partial Thromboplastin Time (APTT)
- Antithrombin IIIa
- Batroxobin
- D-dimer
- Deficient Plasmas
- Derived Fibrinogen
- Fibrinogen
- Heparin
- Lupus Anticoagulants
- Prothrombin Time (PT)
- Plasminogen
- Protein C-clotting
- Protein C-chromogenic
- Thrombin Time
- von Willebrand factor

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011665

(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)

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