JAN 1 8 2002

K013155

510(k) Summary of Safety and Effectiveness
Dade® Thromboplastin C Plus
September 20, 2001

Dade Behring Inc.
13251 NW 9th Terrace
Miami, FL 33182
Contact Person: Radames Riesgo at 305.480.7558 or by facsimile at 305.552.5288.

Trade or Proprietary Name: Dade® Thromboplastin C Plus

Common or Usual Name: Prothrombin time assay

Classification Name: Prothrombin Time Test (21 CFR § 864.7750)

Registration Number:

Location	*Registration Number*
Manufacturer Dade Behring Marburg GmbH Emil-von-Behring Str. 76 D-35001 Marburg, Germany	9610806
Distributor Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, DE 19714-6101	2517506

The modified product is an *in vitro* diagnostic test for the determination of prothrombin time and prothrombin time-based assays. Dade® Thromboplastin C Plus is a lyophilized preparation of dried rabbit brain with calcium and stabilizers. The reagent initiates clotting via the extrinsic common pathway in a global screening test, the prothrombin time (PT). The obtained clotting time detects single or combined deficiencies of the extrinsic coagulation system indicative of hereditary and acquired coagulation disorders, is a sensitive monitoring test for oral anticoagulation therapy and an assay for specific coagulation factors.

Dade® Thromboplastin C Plus is substantially equivalent in intended use for fibrinogen determination to Multifibren™ U (K934326). Both the proposed product and the predicate device are intended to provide results of the fibrinogen concentration present in citrated human plasma.

Comparative performance studies involving different photo-optical coagulation analyzers were conducted to evaluate the performance of both reagents for the determination of fibrinogen concentration in specimens.

The results of the performance studies are summarized in the tables below.

Summary of Method Comparison Studies between Dade® Thromboplastin C Plus and Multifibren™ U

Analyzers	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
BCT™/BCT™	171	0.951	Y = 1.03X – 0.40
BCS™/BCT™	165	0.935	Y = 1.09X – 0.59
Sysmex® CA-1500/BCT	166	0.965	Y = 1.09X – 0.32
Sysmex® CA-6000/BCT	103	0.943	Y = 1.08X – 0.65
Sysmex® CA-500/BCT	176	0.975	Y = 1.12X – 0.41

Summary of Precision Study
Derived Fibrinogen Determination on
Sysmex® Automated Coagulation Analyzer CA-1500

Assay	Control Level	n	Mean	Within Run %CV	Between Run %CV	Total %CV	Max. Error Criteria %CV
Derived Fibrinogen (Dade® Thromboplastin C Plus)	CPN	40	1.8	5.5	1.6	5.4	10
	CPP	40	0.7	1.1	0.4	1.1	
	NPP	40	2.9	4.6	1.7	4.6	
	PPP	40	4.6	4.7	1.1	4.5	

CPN: Control Plasma N
CPP: Control Plasma P
NPP: Normal plasma pool
PPP: Pathological plasma pool

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rebecca S. Ayash
Director, Regulatory Affairs and Compliance
Dade Behring Inc.
Glasgow Site, P.O. Box 6101
Newark, DE 19714-6101

JAN 1 8 2002

Re: k013155
Trade/Device Name: Dade® Thromboplastin C Plus
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: December 13, 2001
Received: December 14, 2001

Dear Ms. Ayash:

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.

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

510(k) Number (if known): K013155

Device Name: Dade® Thromboplastin C Plus

Indications for Use:

Dried Rabbit Brain Thromboplastin with Calcium. For use in prothrombin time (PT) determinations and prothrombin time based assays.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013153

Prescription Use ✓ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**