

MAR - 1 2000

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

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 21CFR§807.92.

Submitter's Name: Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: December 20, 1999

Name of Product: Dimension® Special Protein Calibrator

FDA Classification Name: Calibrator

Predicate Device: Beckman CAL 1

Device Description: The Dimension® Special Protein Calibrator is a liquid human serum-based product supplied as a kit of ten vials; two at each of five levels.

Intended Use: The Special Protein Calibrator is intended to be used to calibrate the complement component, C₃ (C3), complement component, C₄ (C4), Transferrin (TRNF), Immunoglobulin G (IGG), Immunoglobulin A (IGA), and Immunoglobulin M (IGM) methods on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

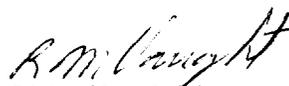
<u>Device</u>	<u>Beckman CAL 1</u>	<u>Dimension® Special Protein Calibrator</u>
Intended Use:	Calibrator	Calibrator
Analytes:	Complement C ₃ (C3) Complement C ₄ (C4) Transferrin (TRF) Immunoglobulin G (IgG) Immunoglobulin A (IgA) Immunoglobulin M (IgM) Alpha ₁ -acid glycoprotein (AAG) Haptoglobin (HPT) Kappa light chain (KAP) Lambda light chain (CAM)	Complement C ₃ (C3) Complement C ₄ (C4) Transferrin (TRNF) Immunoglobulin G (IGG) Immunoglobulin A (IGA) Immunoglobulin M (IGM)
Matrix:	Human serum base	Human serum base
Form:	Liquid	Liquid
Volume:	3.0 mL per vial, reconstituted	1.5 mL per vial
Levels:	1 level	5 levels
Reference:	IFCC, CRM 470	IFCC, CRM 470

Comments on Substantial Equivalence:

Both the Beckman CAL 1 and the Dimension® Special Protein Calibrator are intended as calibrators for C3, C4, Transferrin, IgG, IgA, and IgM methods.

Conclusion:

The Dimension® Special Protein Calibrator is substantially equivalent to the Beckman CAL 1 calibrator based on the comparison discussed above.



Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: December 20, 1999



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 1 2000

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K994291
Trade Name: Dimension® Special Protein Calibrator
Regulatory Class: II
Product Code: JIT
Dated: December 20, 1999
Received: December 21, 1999

Dear Mr. Vaught:

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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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 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' and 'G'.

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

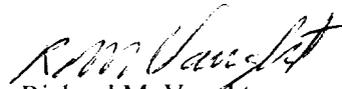
INDICATIONS FOR USE STATEMENT

Device Name:

Dimension® Special Protein Calibrator

Indications for Use:

The Special Protein Calibrator for the Dimension® clinical chemistry system is an *in vitro* diagnostic device intended to establish points of reference that are used in determination of human IgA, IgG, IgM, complement C3, complement C4, and Transferrin values.



Richard M. Vaught
Regulatory Affairs and Compliance Manager

February 17, 2000

(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 _____

K994291

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-counter Use _____

(Optional format 1-2-96)