

3/22/99

K990554

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 21 CFR 807.92.

Submitter's Name: Cathy P. Craft
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: February 3, 1999

Name of Product: Dimension® Special Protein Calibrator

FDA Classification Name: Calibrator

Predicate Device: Beckman CAL I

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

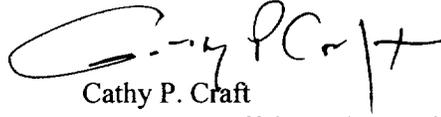
Intended use: The Dimension® Special Protein Calibrator is intended to be used to calibrate the Immunoglobulin G (IGG), Immunoglobulin A (IGA), and Immunoglobulin M (IGM) methods on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

<u>Item</u>	<u>Beckman CAL I</u>	<u>Dimension® Special Protein Calibrator</u>
Intended Use	Calibrator	Calibrator
Analytes	Immunoglobulin G (IgG) Immunoglobulin A (IgA) Immunoglobulin M (IgM) Alpha ₁ -acid glycoprotein (AAG) Complement C ₃ (C3) Complement C ₄ (C4) Haptoglobin (HPT) Kappa light chain (KAP) Lambda light chain (CAM) Transferrin (TRF)	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 I and the Dimension® Special Protein Calibrator are intended to be used as calibrators for IGG, IGA, and IGM methods.

Conclusion: The Dimension® Special Protein Calibrator is substantially equivalent to the Beckman Immunoglobulin Calibrator based on the comparison discussed above.



Cathy P. Craft
Regulatory Affairs and Compliance Manager
Date: February 8, 1999



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cathy P. Craft
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Re: K990554

Trade Name: Dimension® Special Protein Calibrator
Regulatory Class: II
Product Code: JIT
Dated: February 8, 1999
Received: February 22, 1999

Dear Ms. Craft:

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.

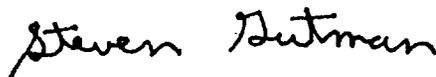
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, prominent "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 for use in an *in vitro* test system to establish points of reference that are used in determination of values in the measurement of human substances.

Cathy P. Craft
Regulatory Affairs and
Compliance Manager

February 8, 1999

(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 K990554

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-counter Use _____