4/16/99

K990824

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: Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: March 11, 1999

Name of Product: Dimension® Revised C-Reactive Protein Calibrator

FDA Classification Name: Calibrator

Predicate Device: Dade Behring N CRP Standard SY, K962406

Device Description: The Dimension® Revised C-Reactive Protein Calibrator is a liquid product. Level 1 contains bovine serum albumin. Levels 2-5 contain human serum base product with added human C-Reactive Protein. The kit consists of ten vials; two at each of five levels.

Intended use: The Dimension® Revised C-Reactive Protein Calibrator is intended to be used to calibrate the Revised C-Reactive Protein (RCRP) method on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

Item	N CRP Standard SY	Revised C-Reactive Protein Calibrator
Intended Use	Calibrator	Calibrator
Analytes	C-Reactive Protein (CRP)	C-Reactive Protein (CRP)
Matrix	human serum base	L-1: bovine serum albumin L 2-5: human serum base
Form	lyophilized	liquid
Volume	0.5 mL per vial, reconstituted	1.0 mL per vial
Levels	1 levels	5 levels
Reference	Primary standard -- IFCC CRM 470	Primary standard – IFCC CRM 470

Comments on Substantial Equivalence: Both the N CRP Standard SY and the Dimension® Revised C-Reactive Protein Calibrator are intended to be used as calibrators for C-Reactive Protein.

Conclusion: The Revised C-Reactive Protein Calibrator is substantially equivalent to the N CRP Standard SY based on the comparison discussed above.

Lorraine Piestrak Lorraine Piestrak
Quality Assurance and Compliance Manager
March 11, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1999

Ms. Lorraine Piestrak
Quality Assurance and
Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K990824
Trade Name: Dimension® Revised C-Reactive Protein Calibrator
Regulatory Class: I
Product Code: JIT
Dated: March 11, 1999
Received: March 12, 1999

Dear Ms. Piestrak:

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.

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 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 For Use Statement

Device Name: Revised C-Reactive Protein Calibrator

Indications for Use:

The Revised C-Reactive Protein Calibrator for the Dimension® Clinical Chemistry System is a device intended to calibrate the Dimension® clinical chemistry system for the Revised C-Reactive Protein (RCRP) method.

Lorraine Piestrak
Quality Assurance and
Compliance Manager

March 11, 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 K790824

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)