K053104

DEC 2 3 2005

510(k) Summary for the
Dimension® CardioPhase® high sensitivity CRP Calibrator
(CCRP Calibrator - RC434)

A. 510(k) Number:

B. Analyte: C-Reactive Protien Calibrator

C. Type of Test: Calibrator Material

D. Applicant:
Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

E. Proprietary and Established Names:
Dimension® CardioPhase® high sensitivity CRP Calibrator (CCRP Calibrator- RC434)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – CALIBRATOR

2. Classification: Class II

3. Product Code: JIS - CALIBRATORS, PRIMARY

4. Panel: CLINICAL CHEMISTRY

G. Intended Use:
1. Intended use(s):

The Dimension® CCRP Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® ***CardioPhase***® high sensitivity C-reactive protein (Cat. No. RC434) method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

2. Indication(s) for use:

The Dimension® CCRP Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® ***CardioPhase***® high sensitivity C-reactive protein (Cat. No. RC434) method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description:

The high sensitivity C-reactive protein Calibrator is a liquid bovine serum albumin-based product. Levels 2 -5 contain a human C-reactive protein.

I. Substantial Equivalence Information:

1. Predicate device name(s): N Rheumatology Standard SL on the BN Systems.

2. Predicate K number(s): K964527

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	Dimension® CardioPhase® (CCRP) Calibrator	**N Rheumatology Standard SL**
Intended Use	The Dimension® CCRP Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® ***CardioPhase®*** high sensitivity **C-reactive protein method** for the Dimension® clinical chemistry system with the heterogeneous immunoassay module.	Establishment of reference curves for the immunonephelometric determination of rheumatoid factors (RF), anti-streptolysin O (ASL) and **C-reactive protein (CRP)** using the BN* Systems.
Traceability	IFCC/BCR/CAP CRM 470	IFCC/BCR/CAP CRM 470

Differences		
Item	**Device**	**Predicate**
	Dimension® CardioPhase® hsCRP (CCRP) Calibrator	**N Rheumatology Standard SL**
Matrix	liquid bovine serum albumin-based	human sera based
Number of levels	Multi-Point 5 levels provided	Multi-Point 1 level provided (instrument prepares 6 standard dilutions)
Reference Curve Fit Calculation	Logit	4 Parameter Logit Log

J. Standard/Guidance Document Referenced:

1. Guidance;
Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays
Document issued on: September 22, 2005

2. Standards;

GP22-A	Continuous Quality Improvement Essential Management Approaches
CEN 13640	Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000	Medical devices -Application of risk management to medical devices
ISO 15223	Medical devices – Symbols to be used with medical device labeling and information to be supplied

K. Test Principle:
The Dimension® CCRP Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® ***CardioPhase***® high sensitivity C-reactive protein (Cat. No. RF434) method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. The hsCRP method is a one step enzyme immunoassay based on the "sandwich" principle.

L. Performance Characteristics:

1. Stability

Calibrator shelf life is determined by comparing results of the product stored at 4°C with product stored at -70°C to ensure that analytical system drift is dissociated with calibrator drift. Linear regression across the shelf life interval for each test sample versus test day will have non-significant slopes ($p > 0.05$) or observed drift within +/-5% for non-zero samples and +/-0.05 mg/L at 0 mg/L CRP over a 12 month interval The shelf life of the product will be 6 months after the successful completion of 7 months of real time stability on three lots of product.

2. Traceability:

The assigned values of the CCRP calibrator are standardized to the International Federation of Clinical Chemistry (IFCC) International Reference Preparation for Plasma Proteins, the Community Bureau of Reference (BCR) and the College of American Pathologists (CAP). The basis of this international standardization is the IFCC/BCR/CAP reference preparation for 14 human serum proteins (Lot No. 91/0619=CRM470=RPPHS 91/0619) (lot V).

3. Value Assignment

Three Dimension® clinical chemistry analyzers are calibrated with the approved CCRP Masterpool. The acceptable recovery of an approved CCRP Calibrator lot must be obtained. Test calibrator levels are then tested on three separate analyzers with different CCRP flex lots. The grand mean of all 5 replicate test means of all 9 curves is the value assignment for each Calibrator Level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 2005

Ms. Andrea M. Tasker
Regulatory Affairs and Compliance
Dade Behring Inc.
Glasgow Business Community
PO Box 6101, Building 500
Newark, DE 19714-6101

Re: k053104
Trade/Device Name: Dimension® ***Cardio***Phase® high sensitivity C-reactive protein Calibrator (CCRP Calibrator –RC434)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: November 2, 2005
Received: November 4, 2005

Dear Ms. Tasker:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): k053104

Device Name:
Dimension® ***Cardio***Phase® high sensitivity C-reactive protein Calibrator
(CCRP Calibrator - RC434)

Indications for Use:

The Dimension® CCRP Calibrator is an in vitro diagnostic product intended to be used to calibrate the Dimension® ***Cardio***Phase® high sensitivity C-reactive protein (Cat. No. RF434) method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

Ann Choppie

Division

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K053104

Prescription Use X **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)