510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k053104

B. Purpose for Submission:

New calibrator

C. Measurand:

Calibrator for CRP assay

D. Type of Test:

Calibrator

E. Applicant:

DADE BEHRING, INC.

F. Proprietary and Established Names:

DIMENSION CARDIOPHASE HIGH SENSITIVITY C-REACTIVE PROTEIN CALIBRATOR

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
Calibrator, Primary (JIS)	Class II	21 CFR § 862.1150, Calibrator.	75 CLINICAL CHEMISTRY (CH)

H. 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. 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.

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.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.

3. Special conditions for use statement(s):

   Prescription use

4. Special instrument requirements:

   Dimension® clinical chemistry systems

I. 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.10 vials in each box. There are 5 levels and each vial contains 1.0 mL each.

Human source material was tested and found negative for HIV 1 and 2, HBV and HCV using FDA approved methods.

J. Substantial Equivalence Information:

K964527 N Rheumatology Standard SL (BN System)

K. Standard/Guidance Document Referenced (if applicable):

- Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A)
- Stability Testing of In Vitro Diagnostic Reagents (13640)
- Medical devices - Application of risk management to medical devices (14971:2000)
- Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied (15223)
- Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use http://www.fda.gov/cdrh/ocd/guidance/4444.html
- Guidance for Industry - Review Criteria for Assessment of C‑Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays OIVD DCTD http://www.fda.gov/cdrh/oivd/guidance/1246.html

L. Test Principle:

The general calibration procedure is described in the Dimension® system manual. All sampling , reagent delivery, mixing, separation, processing and printing of results are automatically performed by the Dimension® system with the heterogeneous immunoassay module. The following information should be considered when calibrating the CCRP method:

Assay Range: 0.1 – 15.0 mg/L

Calibrator Target Levels: 0, 1, 6, 10, 17 mg/L (These levels may vary based on lot to lot assignment.)

Calibration Scheme, Replicates: 4 @ level 1, 3 @ level 2 and 3, 2 @ level 4 and 3 @ level 5 (This scheme is performed automatically by the instrument)

Calibration Frequency: Each new reagent cartridge lot. Every 30 days for any lot.

Preparation: Allow liquid calibrator to equilibrate to room temperature (22–28°C) and swirl to mix before use.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:
   Not Applicable

   b. Linearity/assay reportable range:
   Not Applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   The assigned values 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)

   Calibrator Stability Testing Protocol :
   Study Duration: 13 months
   Reference: Identical lot of product stored at -70°C
   - Testing Replicates: Five (5) replicates per level
   - Testing Frequency: Product is stored at 2 - 8 °C and throughout testing cycle

- and tested at days 0, 1, 2, 3, 7, 14, 28, 63, 91, 189, 273, 301, 364, 392. The control material is stored at -70 °C and tested at the same frequency.
- Freeze/Thaw Testing: Product is frozen and thawed three (3) times then stored at 4°C. Testing occurs on days 28, 91, 189, 273, 364, 392.
- Stressed Stability: Product is stored at 25 °C for 2 days, then 30°C for 1 day at the beginning of the study. The product at the elevated temperatures is then redistributed at 2 -8 °C after the third day. The vials are then tested at days 28, 91, 189, 273, 364, 392.
- Acceptance Criteria: 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.

d. Detection limit:
Not Applicable

e. Analytical specificity:
Not Applicable

f. Assay cut-off:
Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:
Not Applicable

b. Matrix comparison:
Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not Applicable

*b. Clinical specificity**:***
Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not Applicable

4. Clinical cut-off**:**
Not Applicable

5. Expected values/Reference range:
   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.