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

A. 510(k) Number:

k061750

B. Purpose for Submission:

Clearance to market an in vitro calibrator for high and low density cholesterol

C. Measurand:

Calibrators for HDL and LDL cholesterol

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ System Lipid Calibrator: LIPID CAL

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1150: Calibrator

2. Classification:

   Class II

3. Product code:

   JIX

4. Panel:

   (75) Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use.

2. Indication(s) for use:

   The LIPID CAL is an in vitro diagnostic product for the calibration of high density lipoprotein cholesterol (HDLC) and low density lipoprotein cholesterol (LDLC) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

   For Prescription use

4. Special instrument requirements:

   Dimension Vista™ System

I. Device Description:

LIPID CAL is a liquid, multi-analyte, human albumin based product containing human lipoproteins and bovine gamma globulins. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 1.5 mL.

All human source material was tested by FDA-approved methods for the presence of antibodies to Human Immunodeficiency Virus Type 1(HIV-1) and Type 2 (HIV-2), as well as for Hepatitis B Surface Antigen (HBsAg) and antibody to Hepatitis C Virus (HCV), and found to be negative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® HDL Calibrator

2. Predicate 510(k) number(s):

   k983850

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	HDL	Same

Similarities		
Item	Device	Predicate
Form	Liquid	Liquid

Differences		
Item	Device	Predicate
Analyte	LDL	Absent
Traceability	National Cholesterol Education Program (NCEP) reference method.	NBS SRM 911 a
Levels	2	3
Matrix	Human albumin based product containing human lipoproteins and bovine gamma globulins.	Stabilized aqueous solution containing cholesterol.

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

Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

CEN 13640: Stability testing of In-Vitro Diagnostic Devices

ISO 14971:2000: Medical devices -Application of risk management to medical devices

L. Test Principle:

Not applicable. This submission is for clearance of a calibrator.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Not applicable

   b. *Linearity/assay reportable range:*

   Not applicable

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

   The company verified the claimed stability of their proposed device using a combination of real-time and stress testing. The data supplied by the company supports their claim for a 12 month refrigerated shelf life.

The company assessed the open vial stability of their device by using real-time testing. The data supplied by the company supports their claim for a 30 day opened shelf life.

The company accomplishes value assignment via comparison to a reference laboratory method. The low concentration human HDL and LDL calibrators are prepared gravimetrically and stored at -70 °C as the base matrix. At the time of manufacture, additional HDL and LDL are added to the base matrix to make the high concentration calibrator. The company assigns values to both low and high concentration material using a total of 90 measurements spread across multiple instruments. Instruments are calibrated using material with values assigned by a National Cholesterol Education Program (NCEP) reference method.

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.