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

A. 510(k) Number:

k061885

B. Purpose for Submission:

510(k) premarket notification package to manufacture and market the Dimension Vista™ System Total Triiodothyronine Calibrator (T3CAL-KC250).

C. Measurand:

Calibrator for Total Triiodothyronine (T3)

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring, inc.

F. Proprietary and Established Names:

Dimension Vista™ System Total Triiodothyronine Calibrator (T3CAL-KC250).

G. Regulatory Information:

1. Regulation section:

   862.1150 – Calibrator

2. Classification:

   Class II

3. Product code:

   Calibrator, Secondary (JIT)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. <u>Intended use(s):</u>

   See indications for use below.

2. <u>Indication(s) for use:</u>

   The T3 CAL is an in vitro diagnostic product for the calibration of Total Triiodothyronine (T3) method on the Dimension Vista™ System.

3. <u>Special conditions for use statement(s):</u>

   For prescription use

4. <u>Special instrument requirements:</u>

   Dimension Vista™ System

I. Device Description:

The T3 CAL is a liquid, human serum based product containing L-triiodothyronine. The kit consists of six vials, three vials of Calibrator A (2.0 mL per vial) and three vials of Calibrator B (1.5 mL per vial). T3 CAL is ready for use, no preparation is required.

All human source materials were tested by FDA approved methods and found to be negative for antibodies to HIV-1/2, HbsAg, and HCV.

J. Substantial Equivalence Information:

1. <u>Predicate device name(s):</u>

   Dimension® Total Triiodothyronine Calibrator

2. <u>Predicate 510(k) number(s):</u>

   k032697

3. <u>Comparison with predicate:</u>

Similarities		
Item	Dimension Vista™ System Total Triiodothyronine Calibrator (T3CAL-KC250)	Dimension® Total Triiodothyronine Calibrator
Traceability	Traceable to United States Pharmacopeia (USP) L-triiodothyronine (USP Catalog #36800).	Traceable to United States Pharmacopeia (USP) L-triiodothyronine (USP Catalog #36800).
Form/Matrix	Liquid stripped human serum based.	Liquid stripped human serum based.

Differences		
Item	Dimension Vista™ System Total Triiodothyronine Calibrator (T3CAL-KC250)	Dimension® Total Triiodothyronine Calibrator
Intended use	The T3 CAL is an in vitro diagnostic product for the calibration of Total Triiodothyronine (T3) method on the Dimension Vista™ System.	The Dimension@ Total Triiodothyronine (T3) Calibrator (RC4 14) is intended for use in the calibration of the Total Triiodothyronine (T3) method on the Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module.
Levels	Two levels	Five levels

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

CEN 13640, Stability Testing of In Vitro Diagnostic Reagents

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

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

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

L. Test Principle:

Not Applicable

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):*

   <u>Traceability</u>

   The assigned values of the calibrators are traceable to United States Pharmacopeia (USP) L-triiodothyronine (USP Catalog #36800).

   <u>Value Assignment</u>

   The master pool is manufactured by weighing USP T3 into stripped human serum at five levels. The master pool bottle values are assigned by calibration with a previous master pool using multiple replicates on multiple instruments.

   The commercial calibrators are manufactured by weighing purified T3 into stripped human serum at two levels. Bottle values are assigned by calibration with the master pool using multiple replicates on multiple instruments.

   <u>Stability</u>

   Protocols and acceptance criteria were described and found to be acceptable.

   d. *Detection limit:*

   Not Applicable

   e. *Analytical specificity:*

   Not Applicable

   f. *Assay cut-off:*

   Not Applicable

2. <u>Comparison studies:</u>

   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.