

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

- A. 510(k) Number:** K032697
- B. Analyte:** Triiodothyronine (T3)
- C. Type of Test:** N/A
- D. Applicant:** Dade Behring Inc.

E. Proprietary and Established Names: Dade Behring Dimension® Total Triiodothyronine (T3) Calibrator (RC414)

F. Regulatory Information:

1. Regulation section: §862.1150, Calibrator, Primary
2. Classification: Class II
3. Product Code: JIS
4. Panel: 75 (Chemistry)

G. Intended Use:

1. Indication(s) for use:

The T3 Calibrator is intended for use in the calibration of Total Triiodothyronine (T3) method on the Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module.

2. Special condition for use statement(s): None
3. Special instrument Requirements: Dade Behring Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module.

H. Device Description:

The Dimension® Total Triiodothyronine (T3) Calibrator (RC414) is a liquid product. The kit consists of 10 vials, two each at levels 1 through 5. Level 1 vials contain 2mL of stripped human serum. Vials for levels 2 through 5, contain 1 mL with concentrations of L-Triiodothyronine in a stripped human serum base.

I. Substantial Equivalence Information:

1. Predicate device name(s): Opus Total T3 Calibrator
2. Predicate K number(s): K953160
3. Comparison with predicate:

	Dimension® T3 Calibrator	Opus Total T3 Calibrator
Intended Use	Calibrator	Calibrator
Analyte	T3	T3
Matrix	Stripped human serum base	Stripped human serum base
Form	Liquid	Liquid
Volume	2 mL per vial @ level 1, 1 mL per vial @ levels 2-5	2 mL per vial @ level 1, 1 mL per vial @ levels 2-6
Levels	5 levels @ 0, 1, 2, 4, 6.5 ng/mL	6 levels @ 0, 0.5, 1, 2, 4, 6 ng/mL

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

FDA guidance “Abbreviated 510(k) submissions for In Vitro Diagnostic Calibrators”

K. Test Principle: N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:* N/A
 - b. *Linearity/assay reportable range:* N/A
 - c. *Traceability (controls, calibrators, or method):*

The assigned values are referenced to USP L-Triiodothyronine (USP Catalog # 36800). Users of this product will be notified if there is a change in the assigned values. Systeme International d’Unites Conversion factor: ng/mL x 1.536 = nmol/L

- d. *Detection limit:* N/A
- e. *Analytical specificity:* N/A

f. Assay cut-off: N/A

2. Comparison studies:

a. Method comparison with predicate device: N/A

b. Matrix comparison: N/A

3. Clinical studies:

a. Clinical sensitivity: N/A

b. Clinical specificity: N/A

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

4. Clinical cut-off: N/A

5. Expected values/Reference range:

The following table shows the calibrator values obtained on the Dimension® Clinical Chemistry System with Heterogeneous Immunoassay Module. Please note the assignment is absolute, there is no range:

	<i>Assigned Value</i>	<i>Units</i>	<i>Assigned Value</i>	<i>SI Units</i>
<i>Level 1</i>	<i>0</i>	<i>ng/mL</i>	<i>0</i>	<i>nmol/L</i>
<i>Level 2</i>	<i>1</i>	<i>ng/mL</i>	<i>1.5</i>	<i>nmol/L</i>
<i>Level 3</i>	<i>2</i>	<i>ng/mL</i>	<i>3.1</i>	<i>nmol/L</i>
<i>Level 4</i>	<i>4</i>	<i>ng/mL</i>	<i>6.1</i>	<i>nmol/L</i>
<i>Level 5</i>	<i>6.5</i>	<i>ng/mL</i>	<i>9.9</i>	<i>nmol/L</i>

M. Conclusion:

Based on the information provided, I recommend that the Dade Behring Dimension® Total Triiodothyronine (T3) Calibrator is substantially equivalent to the Opus Total T3 Calibrator (K953160) predicate device.