

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k072717

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for direct and total bilirubin

D. Type of Test:

Calibrator material

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista® System BILI Calibrator

G. Regulatory Information:

1. Regulation section:

21§ 862.1150 - Calibrator

2. Classification:

Class II

3. Product code:

JIT

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The BILI CAL is an *in vitro* diagnostic product for the calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista® System.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use on the Dade Behring Dimension Vista® System

I. Device Description:

The BILI calibrator is a two level calibrator material. Level 1 calibrator is purified system water, which is provided on-board the Dimension Vista® and contains no bilirubin. Level 2 is a liquid, bovine serum albumin based material spiked with ditaurobilirubin and traceable to NIST Standard Reference material 916a.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista™ TDBIL Calibrator

2. Predicate K number(s):

k061839

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The BILI CAL is an <i>in vitro</i> diagnostic product for calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista® System	Same
Traceability	NIST Standard Reference Material (SRM) 916a	Same

Similarities		
Item	Device	Predicate
Analyte	Ditaurobilirubin	Same
Levels	Level 1 is on-board, purified system water; Level 2 Total Bilirubin 27.5 mg/dL	Same

Differences		
Item	Device	Predicate
Matrix	Bovine Serum	Human Serum
Levels	Direct Bilirubin Level 2 is 17.5 mg/dL	Direct Bilirubin Level 2 is 19.25 mg/dL
Form	Liquid	Lyophilized
Volume	3 vials, 2.5 mL each	3 vials, 1 mL each

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

FDA Guidance: Abbreviated 510(k) Submissions for *In Vitro* Diagnostic Calibrators, 2/22/98

L. Test Principle:

Not applicable

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):*

Traceability:

The calibrator is traceable to NIST SRM 916a. The values are assigned by spiking master serum pools with varying amount of ditaurobilirubin and analyzing repeated measurements on the instrument calibrated with NIST material. Then the working bovine serum calibrator material is prepared by spiking with ditaurobilirubin and analyzing repeated measurements for total and direct bilirubin on the instrument calibrated with the master pools.

Stability:

Opened-unopened stability, freeze-thaw stability, real-time stability, and accelerated stability studies were performed and found to meet the sponsor's acceptable criteria.

Expected values:

The assigned value is provided in the labeling.

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:

A total of 35 plasma samples and 32 serum samples were assayed on the instrument in duplicate to compare the results of the proposed calibrator material on the y axis with the current calibrator material on the x axis. The results yielded the following linear regression equations:

Method	Slope	Intercept	Correlation coefficient	N
Total bili	1.004	-0.010	1.000	67
Direct bili	0.981	-.035	0.999	67

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.