

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

A. 510(k) Number:

k103360

B. Purpose for Submission:

New device

C. Measurand:

Calibrator materials for Dimension Vista® Digitoxin Assay

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics

F. Proprietary and Established Names:

Dimension Vista® Digitoxin Calibrator – DGTX CAL

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIT – Calibrator, Secondary

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The DGTX CAL is an *in vitro* diagnostic product for the calibration of digitoxin on the Dimension Vista® System.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dimension Vista® 1500 analyzer

I. Device Description:

The DGTX CAL is an *in vitro* diagnostic device that contains 5 levels of Digitoxin in a buffer/protein (bovine serum with proprietary preservative and stabilizer) matrix. The vials contain 2.0 mL each and are packaged in sets of 10 vials (2 of each level).

Level	Target Value (ng/mL)
Calibrator A	0.0
Calibrator B	10.0
Calibrator C	20.0
Calibrator D	40.0
Calibrator E	82.0

J. Substantial Equivalence Information:

1. Predicate device name(s):

Siemens Healthcare Diagnostics, Dimension Drug Calibrator II

2. Predicate K number(s):

k033809

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Same	An <i>in vitro</i> diagnostic product intended for calibration.
Matrix	Same	Bovine Serum base
Levels	Same	5 Levels
Volume per Vial	Same	5 mL
Preparation	Same	Liquid
Storage	Same	2 – 8 °C
Differences		
Item	Device	Predicate
Analytes	<ul style="list-style-type: none"> • Digitoxin 	<ul style="list-style-type: none"> • Acetaminophen (ACTM) • Carbamazepine (CRBM) • Digitoxin (DGTX) • Gentamicin (GENT) • Lidocaine (LIDO) • N-acetylprocainamide (NAPA) • Procainamide (PROC) • Tobramycin (TOBR) • Valproic Acid (VALP) • Vancomycin (VANC)

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

None were referenced

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 and Value Assignment

A seven-level Master calibration curve is prepared by gravimetric addition of United States Pharmacopeia (USP) digitoxin to drug-free human serum. The master calibrators are value assigned by the reference measurement procedure, Isotope Dilution Mass Spectrometry (IDMS) at a reference laboratory.

The commercial calibrators are prepared from a stock solution, created by gravimetric addition of commercial digitoxin to bovine serum at a calculated concentration. The stock solution concentration is determined by measuring recovery on a Dimension RxL instrument calibrated with the digitoxin master calibrators (IDMS value assigned).

Stock solution is spiked into bovine serum to create each commercial calibrator material. For each commercial calibrator lot manufactured, values are verified on a Dimension RxL instrument that has been calibrated with the Master calibrators (IDMS value assigned).

The final bottle values are assigned on Dimension RxL and/or Dimension RxL MAX instruments that have been calibrated with the Master calibrators. Value assignment is conducted using three instruments and three reagent lots, and the assigned value is determined from the mean. The bottle value performance is then verified using acceptance criteria on a Dimension Vista 1500 instrument.

Stability

Open-vial and ongoing real-time stability study protocols and acceptance criteria were described. The data support the package insert claims that open-vial DGTX CAL is stable for up to 30 days after opened if stored at 2-8°C, and that storage unopened at 2-8°C provides stability for 12 months. The expiration date listed on each calibrator bottle label reflects this stability time of 12 months.

- 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.