

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

A. 510(k) Number:

k081683

B. Purpose for Submission:

New device

C. Measurand:

Calibrator materials for Cardiac Troponin I

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

LOCI® Cardiac Troponin I Calibrator

G. Regulatory Information:

1. Regulation section:

21CFR 862.1150

2. Classification:

Class II

3. Product code:

JIT

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See Indication for use below.

2. Indication(s) for use:

The LOCI® TNI Calibrator is an *in vitro* diagnostic product for the calibration of the Cardiac Troponin I (TNI) method on the Dimension® EXL™ integrated chemistry system with LOCI® module.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with Dimension® EXL™ integrated chemistry system with LOCI® module.

I. Device Description:

The LOCI® Cardiac Troponin I Calibrator is a liquid, frozen, human serum based product containing native human troponin complex with other components designed to stabilize the product. The calibrator levels and their assigned values are:

	Level 1	Level 2	Level 3	Level 4	Level 5
TNI	0 ng/mL	0.60 ng/mL	6 ng/mL	20 ng/mL	43 ng/mL

The human blood used in the manufacture of these calibrators has been tested using FDA approved methods and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device names(s):

Dimension Vista Cardiac Troponin I Calibrator

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

k053577

3. Comparison with predicate:

Similarities and Differences		
Item	Dimension Vista Cardiac Troponin I Calibrator (predicate device)	LOCI Cardiac Troponin I Calibrator (candidate device)
Intended Use	The CTNI CAL is an in vitro diagnostic product for the calibration of Cardiac Troponin I (CTNI) on the Dimension Vista system	The LOCI TNI CAL is an in vitro diagnostic product for the calibration of the Cardiac Troponin I (TNI) method on the Dimension® EXL™ integrated chemistry system with LOCI module
Analyte and Matrix	Human troponin complex in human serum matrix	Same
Forms	Liquid, frozen form	Same
Calibrator levels	6 levels	5 levels
Traceability	The calibrator is traceable to an internal master pool containing human cardiac troponin complex	Same

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:

Traceability and value assignment for LOCI Troponin I calibrators involves preparation of anchor pools and master pools. The master pools are used to assign individual calibrator lots.

The anchor pools are a 6-level set of primary reference calibrators. They are prepared from native human sera and are assigned values using the Siemens Stratus CS analyzer. The master pools are prepared from a normal human serum pool spiked with human troponin complex to the appropriate concentrations. Values for the Master Pool are derived by multiple analyses against the Anchor Pool calibration curve. Each lot of the LOCI® Cardiac Troponin I Calibrator is prepared the same manner as the master pool and the value assignment is established by measurement against the Master Pool calibration.

Stability: The shelf-life and open-vial stability of the LOCI Cardiac Troponin I Calibrator have been demonstrated using real time data collected from 3 lots of calibrators. The predetermined acceptance criteria and protocols were reviewed and found to be acceptable.

For the LOCI Cardiac Troponin I Calibrator, the sponsor claims a shelf life of 12 months when unopened and stored at -20°C. Once thawed and opened, the calibrator is stable for 24 hours when stored at 2-8°C.

- 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:

The assigned values are printed in the labeling of the calibrator materials.

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.