

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

A. 510(k) Number:

k081103

B. Purpose for Submission:

Add TSH to the existing FT4 calibrator materials

C. Measurand:

Calibrator materials for FT4 and TSH

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

LOCI Thyroid Calibrator

G. Regulatory Information:

1. Regulation section:

21CFR 862.1150

2. Classification:

Class II

3. Product code:

JIX, Calibrator, Multi-analyte mixture

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See Indication for use below.

2. Indication(s) for use:

The LOCI Thyroid Calibrator is an *in vitro* diagnostic product for the calibration of the FT4L and TSHL methods on the Dimension® EXL™ with LM system.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

For use with Dimension® EXL™ with LM system

I. Device Description:

The LOCI Thyroid Calibrator is a liquid, bovine serum albumin based product containing human thyroid stimulating hormone (TSH) and free thyroxine (FT4). The calibrator levels and their assigned values are:

	Level 2	Level 3	Level 4	Level 5	Level 6
FT4L	----	0.8 ng/dL	2.0 ng/dL	4.0 ng/dL	8.4 ng/dL
TSHL	0.00 µIU/mL	4.00 µIU/mL	20.00 µIU/mL	50.00 µIU/mL	105.00 µIU/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):

Siemens LOCI Thyroid Calibrator

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

k073604

3. Comparison with predicate:

Similarities and Differences		
Item	LOCI Thyroid Calibrator (predicate device)	LOCI Thyroid Calibrator (candidate device)
Intended Use	The LOCI Thyroid Calibrator is used to calibrate the Dimension® FT4L method on the Dimension® EXL™ with LM system	The LOCI Thyroid Calibrator is used to calibrate the Dimension® FT4L and TSHL methods on the Dimension® EXL™ with LM system
Analytes and Matrix	The LOCI Thyroid Calibrator contains free thyroxine in a bovine serum albumin matrix	The LOCI Thyroid Calibrator contains human thyroid stimulating hormone and free thyroxine in a bovine serum albumin matrix
Forms	Liquid	Same
Calibrator levels	4 levels (Levels 3 through 6)	5 levels (Level 2 through 6). Levels 3 through 6 are used to calibrate the FT4L method. Levels 2 through 6 are used to calibrate the TSHL method.
Stability	Unopened calibrators are stable until expiration date when stored at 2-8°C. Once opened, stable for 3 months at 2-8°C.	Same
Traceability	The calibrator is traceable to an internal master pool for FT4	The calibrator is traceable to an internal master pool for FT4 and to the WHO standard for TSH.

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

FDA/CDRH Guidance for Industry: Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators, Final- February 22, 1999.

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:

Traceability and value assignment for free thyroxine (fT4) in the calibrator was previously described in k073604 and has not been modified.

Traceability and value assignment for thyroid stimulating hormone involves preparation of anchor pools and master pools. The anchor pool is prepared from WHO TSH 2nd IRP 80/558 reference material spiked into TSH-free serum. Three levels of anchor pool are prepared. A Master Pool is prepared gravimetrically from a commercially available TSH. Values for the Master Pool are derived by multiple analyses against the Anchor Pool calibration curve. LOCI® Thyroid Calibrator value assignment is established by measurement against the Master Pool calibration.

Stability: The shelf-life and open-vial stability of the LOCI Thyroid Calibrator when stored at 2-8°C 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 Thyroid Calibrator, the sponsor claims a shelf life of 12 months when unopened and stored at 2-8°C. Once opened, the LOCI Thyroid Calibrator is stable for 3 months 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 calibrators.

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.