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

A. 510(k) Number:

k100778

B. Purpose for Submission:

Add Triiodothyronine (FT3) to the existing Thyroid Stimulating Hormone (TSH) and Thyroxine (FT4) calibrator materials

C. Measurand:

Calibrator materials for Free Triiodothyronine (FT3) Free Thyroxine (FT4) and Thyroid Stimulating Hormone (TSH)

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics, Inc

F. Proprietary and Established Names:

LOCI Thyroid Calibrator

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX	Class II	21 CFR§ 862.1150	Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   The LOCI Thyroid Calibrator is an *in vitro* diagnostic product for the calibration of the LOCI Free Triiodothyronine (FT3L), LOCI Free Thyroxine (FT4L) and LOCI Thyroid Stimulating hormone (TSHL) methods 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 the Dimension® EXL™ integrated chemistry system with LOCI® Module

I. Device Description:

The LOCI Thyroid Calibrator is a multi-analyte, liquid, bovine serum albumin based product containing triiodothyronine (FT3), thyroxine (FT4) and human thyroid stimulating hormone (TSH). The kit consists of ten vials with two vials per level containing 2.0 mL per vial.

The calibrator levels and their assigned values are:

	Level 2	Level 3	Level 4	Level 5	Level 6
FT4L	-----	0.80 ng/mL	1.60 ng/mL	4.00 ng/mL	8.40 ng/mL
TSHL	0.00 µIU/mL	4.00 µIU/mL	20.00 µIU/mL	50.00 µIU/mL	105.00 µIU/mL
FT3L	0 pg/mL	2 pg/mL	6 pg/mL	15 pg/mL	31.5 pg/mL

*Level 1 is not included in the LOCI Thyroid Calibrator carton. Reagent grade water must be used as the Level 1 calibrator for the FT4L method.

All human source materials used to produce this product have been tested for HbsAg, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA licensed tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens LOCI® THYR Calibrator

2. Predicate 510(k) number (s)

   k073604

Similarities		
Item	LOCI Thyroid Calibrator (candidate device)	LOCI Thyroid Calibrator predicate device (k073604)
Intended Use	Calibration materials for the Dimension® EXL™ integrated chemistry system with LOCI® Module	Same
Analyzer	Dimension® EXL™ with LM system.	Same
Matrix	Bovine Serum Albumin	Same
Levels	5 Levels	Same
Preparation	Liquid	Same
Storage	2-8˚C	Same

Differences		
Item	Candidate Device	Predicate
Analytes	LOCI Free Triiodothyronine (FT3), LOCI Free Thyroxine (FT4L) and LOCI Thyroid Stimulating Hormone (TSHL)	LOCI Free Thyroxine (FT4L) and LOCI Thyroid Stimulating Hormone (TSHL)

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

None 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 for free thyroxine (FT4) and thyroid stimulating hormone (TSH) in the calibrator were previously described in k073604 and k081103 respectively and has not been modified.

Traceability and value assignment for triiodothyronine (FT3) involves preparation of anchor and pools and master pools. The anchor pool is prepared from USP grade 3, 3', 5-triiodo-L-thyronine (T3) spiked in a human serum matrix. Seven levels of anchor pool are prepared. A Master Pool is developed from a bovine albumin based matrix to which different concentrations of 3, 3', 5-triiodo-L-thyronine have been added. Values for the Master Pool are derived by multiple analyses against the Anchor Pool calibration curve. The LOCI Thyroid Calibrator value assignment is established by measurement against the Master Pool calibration.

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 recapped and 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:

An example of the lot specific target values and acceptance range are as follows:

Level	Target	Acceptance Range
TSH	µIU/mL	µIU/mL
2	0.00	-0.005 to +0.005
3	4.00	3.60 – 4.40
4	20.0	18.0 – 22.0
5	50.0	45.0 – 55.0
6	105.0	100 - 120
FT4	ng/mL	ng/mL
2	0.00	-0.10 to +0.30
3	0.80	0.74 -0.90
4	1.60	1.44 -1.76
5	4.00	3.60 – 4.40
6	8.40	8.00 – 9.20
FT3	pg/mL	pg/mL
2	0	-0.5 to +0.5
3	2	1.8 – 2.2
4	6	5.4 – 6.4
5	15	13.5 – 16.5
6	31.5	30.0 – 34.6

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.