510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k082638

B. Purpose for Submission:
This is a new 510(k) to support the integration of a StreamLAB Laboratory Automation System (LAS) (k043546) to the ADVIA Centaur Analyzer (k041133) using the ADVIA Centaur T4 Assay (k905532) to show acceptable performance.

C. Measurand:
Thyroxine

D. Type of Test:
Quantitative Chemiluminescent Immunoassay

E. Applicant:
Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:
Advia Centaur System with StreamLAB Analytical Workcell

G. Regulatory Information:
1. Regulation section:
   21CFR Sec.862.1700 Total thyroxine test system.
   21CFR Sec.- 862.2160-Discrete photometric chemistry analyzer for clinical use.
2. Classification:
   Class II and I, respectively
3. Product code:
   KLI - Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine
   JJE - Analyzer, Chemistry (Photometric, Discrete), For Clinical Use
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See indication(s) for use below.

2. Indication(s) for use:
   The ADVIA Centaur with StreamLAB Analytical Workcell is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include assays based on chemiluminescent technology, such as Thyroxine, along with other various

chemiluminescent assays that may be adaptable to the analyzer depending on the reagent used to induce the chemiluminescent reaction.

The ADVIA Centaur T4 assay is for in vitro diagnostic use in the quantitative determination of thyroxine (T4) in serum on the ADVIA Centaur and ADVIA Centaur XP systems. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

3. <u>Special conditions for use statement(s):</u>
   Prescription use

4. <u>Special instrument requirements:</u>
   ADVIA Centaur with StreamLAB® Analytical Workcell

I. Device Description:
The ADVIA Centaur is a continuous operation, immunochemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens.

The StreamLAB® Analytical Workcell is a laboratory automation system (LAS) designed to automate sample handling and processing in the clinical laboratory.

The ADVIA Centaur with StreamLAB® Analytical Workcell combines the features of both the analyzer and the laboratory automation system.

The StreamLAB routes samples to the Centaur analyzer based on test request information it (StreamLAB) receives from the Laboratory Information System (LIS) and the test map established for the Centaur analyzer. StreamLAB and Centaur communicate sample and analyzer status via Centaur's Laboratory Automation System (LAS) interface. Via its LIS interface, the Centaur analyzer interfaces separately with the hospital's LIS to receive its test instructions (test requests) and to report results for each sample. Centaur's test instructions and test results for each sample are not processed through the StreamLAB.

The StreamLAB performs the following pre and post-analytical functions.
- Sample bar code identification (previously performed by the Centaur)
- Sample transport and tracking
- Sample centrifugation (optional functionality)
- Sample de-capping (optional functionality)
- Sample transport and tracking
- Tube sealing (optional functionality)

The Centaur continues to perform the following functions, when connected to the StreamLAB.

All functions except reading the sample tube bar code. When Centaur is connected to

StreamLAB, samples can be loaded directly onto Centaur and/or loaded onto StreamLAB and routed to Centaur. For samples loaded onto StreamLAB, StreamLAB reads the sample tube bar code (sample identification) and passes it electronically to Centaur via the LAS interface to Centaur.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   ADVIA Centaur T4 Assay
   ADVIA Centaur Analyzer
   StreamLAB Laboratory Automation System (LAS)

2. Predicate 510(k) number(s):
   k905532, k041133, and k043546 respectively

3. Comparison with predicate:

Feature	Predicate device: ADVIA Centaur (K041133)	Proposed device: ADVIA Centaur with StreamLAB Analytical Workcell
Principles of Operation	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	
Optical System	Photomultiplier tube used in photon counting mode	
Sample Containers	Sample cups or primary tubes	Sample cups* or primary tubes
Sample Loading	Load directly onto the Centaur	Load directly onto the Centaur and/or load onto the StreamLAB
Serum & Plasma Sample Preparation	Manually centrifuged samples Manually decapped sample tubes	Manually centrifuged samples or automatically centrifuged samples by the StreamLAB. Manually decapped sample tubes or automatically decapped tubes by StreamLAB.
Sample Identification of Bar-coded Tubes	Tube bar code (identification) is read by the Centaur.	Tube bar code (identification) is read by the Centaur (when tubes are placed directly on the Centaur); or tube bar code read by StreamLAB and communicated electronically to the Centaur (when tubes are loaded onto StreamLAB).
Test Orders	Unidirectional communication with external LIS	
Test Results	Unidirectional communication with external LIS	
Laboratory Automation	Centaur's software communicates with Lab Automation System via LAS interface. Centaur performs direct sampling from tube on the track.	
* Sample cups cannot be used on the StreamLAB. Sample cups must be loaded directly onto the Centaur when connected to the StreamLAB. The StreamLAB does not impact Centaur's capability to accept sample cups.		

K. Standard/Guidance Document Referenced (if applicable):
None were referenced

L. Test Principle:
Chemiluminescence using magnetic-particle solid phase and chemiluminescent label

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*

      The precision of ADVIA Centaur T4 Assay was evaluated by analyzing three levels of a quality control product in triplicate once a day for five (5) days on the Advia Centaur System with StreamLAB Analytical Workcell. The data were analyzed using Analysis of Variance (ANOVA). The results are similar to the precision of the predicate device.

			S.D. (%CV)	
LEVEL	**n**	**Mean**	**Repeatability**	**Within Laboratory**
1	15	5.45 µg/dL	0.13 (2.4)	0.25 (4.7)
2	15	8.26 µg/dL	0.18 (2.1)	0.28 (3.4)
3	15	14.49 µg/dL	0.39 (2.7)	0.44 (3.0

   b. *Linearity/assay reportable range:*
      Provided in k905532

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      Provided in k905532

   d. *Detection limit:*
      Provided in k905532

   e. *Analytical specificity:*
      Provided in k905532
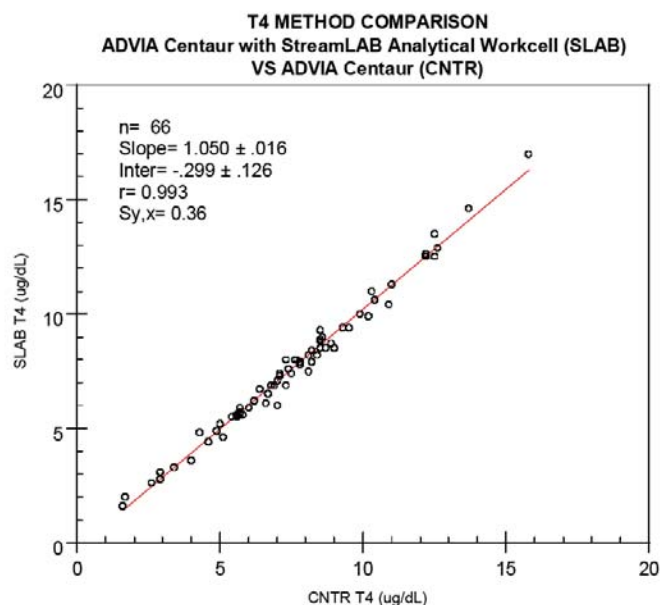
   f. *Assay cut-off:*
      Provided in k905532

2. Comparison studies:
   a. *Method comparison with predicate device:*
      Split-sample method comparison studies were conducted using the ADVIA Centaur T4 Assay. Samples were processed on the predicate device and on the proposed device. The data were analyzed by linear regression and the results are summarized in the table below.

Slope	Intercept	r	Sy,x	n	Range
1.050	-0.299	0.993	0.36	66	1.60 – 17.00 µg/dL

T4 METHOD COMPARISON
ADVIA Centaur with StreamLAB Analytical Workcell (SLAB)
VS ADVIA Centaur (CNTR)

n= 66
Slope= 1.050 ± .016
Inter= -.299 ± .126
r= 0.993
Sy,x= 0.36

   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):

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   Provided in k905532

N. Instrument Name:

Advia Centaur System with StreamLAB Analytical Workcell

O. System Descriptions:

1. Modes of Operation:

   The ADVIA Centaur is a continuous operation, immunochemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens. Pre-analytical and Post-analytical activity is performed by StreamLAB.

   Centaur's software communicates with Lab Automation System via LAS interface. Centaur performs direct sampling from tube on the track.

   The ADVIA Centaur with StreamLAB Analytical Workcell combines the features of both the analyzer and the laboratory automation system.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes _____X_____ or No _____

   The applicant provided software documentation that supports the device was designed and developed under good software LifeCycle processes.

3. Specimen Identification:

   Sample tube bar code (identification) is read by the Centaur (when tubes are placed directly on the Centaur); or sample tube bar code read by StreamLAB and communicated electronically to the Centaur (when tubes are loaded onto StreamLAB).

4. Specimen Sampling and Handling:

   Load directly onto the Centaur and/or load onto the StreamLAB, Manually centrifuged samples or automatically centrifuged samples by the StreamLAB. Manually decapped sample tubes or automatically decapped tubes by StreamLAB. Sample cups cannot be used on the StreamLAB. Sample cups must be loaded directly onto the Centaur when connected to the StreamLAB. The StreamLAB does not impact Centaur's capability to accept sample cups.

5. Calibration:

   Provided in k041133

6. Quality Control:

   Provided in k041133

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.