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

A. 510(k) Number:
k083339

B. Purpose for Submission:
New 510(k) to support the integration of Dimension RxL Max Chemistry system with sample transfer module (k043546) to the ADVIA Modular Automation System using the Calcium Assay (k860021) to show acceptable performance

C. Measurand:
Calcium

D. Type of Test:
Quantitative photometric assay

E. Applicant:
Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:
Dimension® RxL Max® Clinical Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System (LabCell®/WorkCell) with Calcium Reagents

G. Regulatory Information:
1. Regulation section:
   21CFR Sec. 862.1145 Calcium test system
   21CFR Sec. 862.2160 Discrete photometric chemistry analyzer for clinical use
2. Classification:
   Class II and I
3. Product code:
   CIC – cresolphthalein complexone, calcium
   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 Dimension® RxL Max® Clinical Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System is a discrete random access, microprocessor-controlled, integrated instrument/chemistry system that measures a variety of analytes, including enzyme activities in body fluids. The

system menu will include assays, such as Calcium, along with other various assays that may be adaptable to the analyzer depending on the reagent used. Calcium is intended to quantitatively measure Calcium in human serum or plasma. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

3. Special conditions for use statement(s):
   Prescription use

4. Special instrument requirements:
   Dimension® RxL Max® Clinical Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System (LabCell®/WorkCell)

I. Device Description:

The Dimension® RxL Max® Chemistry System is a continuous operation chemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens.

The ADVIA® Modular Automation System (AMAS) is a laboratory automation system (LAS) designed to automate sample handling and processing in the clinical laboratory. AMAS is available as two products, the ADVIA® LabCell® and ADVIA® WorkCell. These LAS systems are made up of the same components and are controlled by common software. The systems differ in their expansion capabilities:

ADVIA® WorkCell is an ADVIA® Automation solution that is limited to three fixed configurations supporting up to a total of five interface stations. ADVIA® LabCell® is customizable ADVIA® Automation solution that is configurable with up to 16 interface stations.

Dimension® RxL Max® Chemistry System (Dimension) with Sample Transfer Module and the ADVIA® Modular Automation System combines the features of both the analyzer and the laboratory automation system.

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

AMAS performs the following pre and post-analytical functions.
• Sample bar code identification (previously performed by the Dimension)
• Sample transport and tracking (pre-Analytical)
• Sample centrifugation (optional functionality)

• Sample de-capping (optional functionality)
• Sample transport and tracking (post-Analytical)

The Dimension continues to perform the following functions, when connected to AMAS.
• All functions except reading the sample tube bar code. When Dimension is connected to AMAS, samples can be loaded directly onto Dimension and/or loaded onto AMAS and routed to Dimension. For samples loaded onto the AMAS, which reads the sample tube bar code (sample identification) and passes it electronically to Dimension via the LAS interface.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   DIMENSION® XL Clinical Chemistry System
   StreamLAB Laboratory Automation System (LAS) and Sample Transfer Module

2. Predicate 510(k) number(s):
   k944093, k043546, k860021

3. Comparison with predicate:

Feature	**Predicate device:** Dimension® RxL Max®	**Proposed device:** Dimension® RxL Max® with ADVIA® Modular Automation System (AMAS)
Intended Use	The Dimension® RxL Max® clinical chemistry system is a discrete, random access, microprocessor-controlled, integrated instrument/chemistry system that measures a variety of analytes, including enzyme activities in body fluids. It can also process high sensitivity chromium-based heterogeneous immunoassays with its HM Module.	The Dimension® RxL Max® clinical chemistry system with automation system is a discrete, random-access, microprocessor-controlled, integrated instrument / chemistry system that measures a variety of analytes, including enzyme activities in body fluids. It can also process high-sensitivity chromium-based heterogeneous immunoassays with its HM Module.
Methodology	Analyzer, chemistry (photometric, discrete), for clinical use has been classified as Class I, JJE by the Clinical Chemistry and Clinical Toxicology Devices Panel, (21 CFR 862.2160). No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act.	Analyzer, chemistry (photometric, discrete), for clinical use has been classified as Class I, JJE by the Clinical Chemistry and Clinical Toxicology Devices Panel, (21 CFR 862.2160). No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act.
Sample Loading	Load directly onto the Dimension	Load directly onto the Dimension and/or load onto AMAS

Sample Types	Serum, Plasma, Cerebral Spinal Fluid, Urine and Whole Blood	Serum, Plasma, Cerebral Spinal Fluid, and Urine
Serum & Plasma Sample Preparation	Manually centrifuged samples Manually de-capped sample tubes	Manually centrifuged samples or automatically centrifuged samples by AMAS. Manually de-capped sample tubes or automatically de-capped tubes by AMAS
Sample Identification of Bar-coded Tubes	Tube bar code (identification) is read by the Dimension	Tube bar code (identification) is read by the Dimension (when tubes are placed directly on the Dimension); or tube bar code read by AMAS and communicated electronically to the Dimension (when tubes are loaded onto AMAS).
Test Orders	Unidirectional communication with external LIS	
Test Results	Unidirectional communication with external LIS	
Laboratory Automation	Dimension's software communicates with Lab Automation System via AMAS interface. Dimension performs direct sampling from tube on the track.	

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

None referenced

L. Test Principle:

The calcium measurement on the Dimension System is done photometrically.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision of RxL Dimension with AMAS was evaluated by analyzing three levels of a quality control product for calcium in replicates of five per day over five (5) days on the Dimension® RxL Max® with and without ADVIA® Modular Automation System (AMAS). The data were analyzed using Analysis of Variance (ANOVA). A p-value less than 0.05 indicates that the difference between the instrument with and without the AMAS attached is statistically significant. The results are similar to the cleared claims. The table below represents the percent coefficient of variation (CV) for samples run within and between days.

			S.D. (%CV)		
LEVEL	n	Mean (mg/dL)	With-in run (mg/dL)	Between day (mg/dL)	Total (mg/dL)
1	25	5.71	0.07 (1.2)	0.03 (0.6)	0.08 (1.4)

2	25	9.92	0.06 (0.6)	0.05 (0.5)	0.08 (0.8)
3	25	13.21	0.09 (0.7)	0.04 (0.3)	0.1 (0.7)

b. Linearity/assay reportable range:
Provided in k860021

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Provided in k860021

d. Detection limit:
Provided in k860021

e. Analytical specificity:
Provided in k860021

f. Assay cut-off:
Provided in k860021

2. Comparison studies:
   a. Method comparison with predicate device:
   Split-sample method comparison studies measuring calcium were conducted using the Dimension® RxL Max® with (the proposed device) and without (predicate device) ADVIA® Modular Automation System (AMAS). The data were analyzed by linear regression and the results are summarized in the table below.

Slope	Intercept	r	Sy,x	n	Range
1.05	-0.4	0.989	0.3	98	5.1 – 13.4 mg/dL

   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 k860021

N. Instrument Name:

Dimension® RxL Max® with ADVIA® Modular Automation System (AMAS)

O. System Descriptions:

1. Modes of Operation:

   The Dimension® RxL Max Chemistry system is a continuous operation chemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens. Pre-analytical and Post-analytical activity is performed by ADVIA® Modular Automation System (AMAS).

   Dimension and AMAS communicates via Lab Automation System interface using its software. Dimension's sample transfer module performs direct sampling from tube on the AMAS track.

   The Dimension RxL Max with AMAS 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 Dimension RxL (when tubes are placed directly on the Dimension RxL); or sample tube bar code read by AMAS and communicated electronically to the Dimension RxL (when tubes are loaded onto AMAS).

4. Specimen Sampling and Handling:
   Load directly onto the Dimension RxL and/or load onto the AMAS, Manually centrifuged samples or automatically centrifuged samples by the AMAS, manually decapped sample tubes or automatically decapped tubes by AMAS.

5. Calibration:
   Provided in k0944093, k043546

6. Quality Control:
   Provided in k860021, k944093, k043546

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.