MAR 9 2009

510(k) Summary of Safety and Effectiveness
Dimension® RxL Max® Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K083339

1. Submitter's Contact Information and Date of Preparation

Submitter's Contact Information:

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
Attn: Lubomyr Shchur
Tel: 914 524-2091

Date of Preparation: February 27, 2009

2. Proprietary Device Name / FDA Classification Name

Dimension® RxL Max® Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System (LabCell®/WorkCell) / Class I: Discrete photometric chemistry analyzer for clinical use (21CFR§862.2160), Product Code JJE

3. Identification of the Predicate Device

Predicate Instrument or Method	510(k)	Product Code
Dimension® XL Clinical Chemistry System	K944093	JJE
Dimension® CA Flex Reagent Cartridge	K860021	CIC

4. Device Description(s):

The Dimension® RxL Max® Chemistry System is a continuous operation chemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens and is a family member of the Dimension® XL Clinical Chemistry System (traditional 510(k) filed in 1994 K944093). The Dimension® RxL Max® Chemistry System has also been cleared with StreamLab Analytical WorkCell and Sample Transfer Module (K043546)

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 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.

5. Device Intended 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.

6. Medical device to which equivalence is claimed

Dimension® RxL Max® Clinical Chemistry System is a family member of the Dimension® XL Clinical Chemistry System (traditional 510(k) filed in 1994 K944093). The devices have same / similar design and modes of operation. The key features are summarized in the following table.

Device Description and Comparison

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.	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.
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 onto AMAS
Sample Types	Serum, Plasma, Cerebral Spinal Fluid, Urine and Whole Blood	Serum, Plasma, Cerebral Spinal Fluid, and Urine

Feature	Predicate Device: Dimension® RxL Max®	Proposed Device: Dimension® RxL Max® with ADVIA® Modular Automation System (AMAS)
Serum and Plasma Sample Preparation	Manually centrifuged samples. Manually de-capped sample tubes	Manually centrifuged samples or automatically centrifuged 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 analyzer.	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 LAS interface. Dimension's Sample Transfer Module performs direct sampling from tube on the track.	

Method Comparison

Split-sample method comparison studies were conducted using the Dimension® RxL MAX® Calcium assay. Samples were processed either directly on the predicate device or on the proposed device. The data were analyzed by linear regression and the results are summarized in the table below.

Method	n	r	Slope	Intercept	Syx	95% CI Slope	95% CI Intercept	% Mean Bias
Ca	98	0.989	1.05	-0.4	0.3	1.02 to 1.08	-3.5 to 2.7	-0.1

7. **Conclusion:**

The proposed Dimension® RxL MAX® with ADVIA® Modular Automation System and the predicate Dimension® RxL Max® (K043546) are substantially equivalent in design, modes of operation, assay performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 9 2009

Siemens Healthcare Diagnostics Inc.
c/o Mr. Lubomyr Shchur,
Regulatory Affairs and Compliance Specialist
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: k083339
Trade/Device Name: Dimension® RxL Max® Clinical Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System (LabCell®/WorkCell) with Calcium Reagents
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Code: CIC, JJE
Dated: February 9, 2009
Received: February 10, 2009

Dear Mr. Shchur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083339

Device Name:

Dimension® RxL Max® Clinical Chemistry System with Sample Transfer Module and the ADVIA® Modular Automation System (LabCell® / WorkCell) with Calcium Reagents

Indication 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.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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