MAY 22 2009

510(k) Summary of Safety and Effectiveness for the

Dimension Vista® Enzymatic Creatinine (ECREA) Flex® Reagent Cartridge

Dimension Vista® Enzymatic Creatinine (ECREA CAL) Calibrator

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

A. 510(k) Number: _k090330_____

B. Date of Preparation: January 27, 2009

C. Proprietary and Established Names:

Dimension Vista® Enzymatic Creatinine Flex® Reagent Cartridge

Dimension Vista® Enzymatic Creatinine Calibrator

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Rose T. Marinelli, Regulatory Technical Specialist

Office Number: (302) 631-8805 Fax Number: (302) 631-6299

E. Regulatory Information:

Dimension Vista® ECREA Flex® Reagent Cartridge:

1. Regulation section: 21 CFR § 862.1225 Creatinine Test System

2. Classification: Class II

3. Product Code: JFY – Enzymatic Method, Creatinine

4. Panel: Clinical Chemistry

Dimension Vista® ECREA CAL:

1. Regulation section: 21 CFR § 862.1150 Calibrator

2. Classification: Class II

3. Product Code: JIT – Calibrator, Secondary

4. Panel: Clinical Chemistry

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® ECREA Flex® reagent cartridge is the Roche Creatinine Plus Reagent previously cleared under K003261.

The predicate device used to demonstrate substantial equivalence to the Dimension® Chem I Cal (DC18B) previously cleared under K860021.

G. Device Description:

The Dimension Vista® ECREA Flex® reagent cartridge is a prepackaged *in-vitro* diagnostic test method that is specifically designed to be used on the Dimension Vista® System. The reagents contained in the Dimension Vista® ECREA Flex® reagent cartridge are: Reagent 1 – TAPS buffer, creatinase, sarcosine oxidase, HTIB; Reagent 2 - TAPS buffer, creatininase, horseradish peroxidase, 4-aminophenazone, and potassium hexacyanoferrate (II).

The Dimension Vista® ECREA CAL is an ECREA CAL is a liquid, bovine serum albumin, based product containing creatinine. The kit consists of six vials, three vials per level (A, B), 2.5 mL per vial. Description of the manufacturing, value assignment and stability testing process are provided in this submission report.

H. Intended Use:

The ECREA method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma and urine on the Dimension Vista® System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.

The ECREA CAL is an in vitro diagnostic product for the calibration of the Enzymatic Creatinine (ECREA) method on the Dimension Vista® System.

I. Substantial Equivalence Information:

The Dimension Vista® ECREA Flex® reagent cartridge and the predicate, Roche Creatinine Plus reagent, were compared. The following table provides a comparison of the important similarities and differences:

Feature	Dimension Vista® ECREA Flex® reagent cartridge	Creatinine Plus Reagent (K003261)
Intended Use	The ECREA method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma, and urine on the Dimension Vista® System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.	Enzymatic in vitro assay for the direct quantitative determination of creatinine in human serum, plasma and urine using Roche clinical chemistry analyzers.
Sample Type	Plasma, serum, and urine	Plasma, serum and urine
Measuring Range	Serum, Plasma - 0.14 -20.0 mg/dL Urine – 2.80 – 400 mg/dL	Serum, Plasma -0.03 – 30 mg/dL Urine – 0.3 – 400 mg/dL
Sample Size	2.7 µL	6 µL
Measurement	Bichromatic end point	Bichromatic end point

The Dimension Vista® ECREA CAL and the predicate, Dimension® Chem I CAL (DC18B), were compared. The following table provides a comparison of the important similarities and differences:

Feature	ECREA CAL	Dimension® Chem I CAL (DC18B) K860021
Intended Use	The ECREA CAL is an *in vitro* diagnostic product for the calibration of the Enzymatic Creatinine (ECREA) method on the Dimension Vista® System.	The Dimension® Chemistry I Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Calcium (CA), Creatinine (CREA/ECRE), Glucose (GLU/GLUC), Urea Nitrogen (BUN), and Uric Acid (URCA) methods.
Analyte	Creatinine	Calcium, Creatinine, Glucose, Urea Nitrogen, Uric Acid
Matrix	Bovine Albumin	Bovine Albumin
Form	Liquid	Lyophilized
Volume	Six vials, three vials per level (A, B), 2.5 mL per vial.	Six vials, two vials per level (1, 2, 3), 2.0 mL per vial
Levels	Three levels: 0.0*, 0.95, 22.0 mg/dL *Level 1 is System Water	Three levels: 0.0, 11.1, 22.4 mg/dL

J. Conclusion:

The Dimension Vista® ECREA Flex® reagent cartridge is substantially equivalent to Roche's Creatinine Plus Reagent (K003261). Comparative testing described in the submission report demonstrates substantial equivalent performance.

The Dimension Vista® ECREA CAL is substantially equivalent to the Dimension® Chem I CAL CREA (K860021). Comparative testing described in the submission report demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Ms. Rose Marinelli
PO Box 6101 MS 514
Newark, DE 19714-6101

MAY 22 2009

Re: k090330
Trade/Device Name: Dimension Vista Enzymatic Creatinine Flex Reagent Cartridge and Dimension Vista Enzymatic Creatinine Calibrator
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY and JIT
Dated: April 24, 2009
Received: April 27, 2009

Dear Ms. Marinelli:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Enclosure

Indications For Use Statement

510(k) Number (if known): K090330

Device Name:

Dimension Vista® Enzymatic Creatinine Flex® Reagent Cartridge

Indications for Use:

The ECREA method is an *in vitro* diagnostic test for the quantitative measurement of creatinine in human serum, plasma and urine on the Dimension Vista® System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for other urine analytes.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K090330

Indications For Use Statement

510(k) Number (if known): K090330

Device Name:

Dimension Vista® Enzymatic Creatinine Calibrator

Indications for Use:

The ECREA CAL is an *in vitro* diagnostic product for the calibration of the Enzymatic Creatinine (ECREA) method on the Dimension Vista® System.

Prescription Use __X__ **(Per 21 CFR 801 Subpart D)**	**AND/OR**	**Over-the-counter Use** _____ **(21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

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