K070727

AUG - 3 2007

510(k) Summary

Submitter information

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Date summary prepared: July 27, 2007

Device Trade or Proprietary Name: ADVIA® Chemistry Enzymatic Creatinine_2 (ECRE_2)

Device Common/Usual Name or Classification Name: Enzymatic Method, Creatinine Test System

Classification Number/Class: JFY / Class II

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

The assigned 510(k) number is: _____

Predicate Devices:

	Predicate Device #1	Predicate Device #2
Device Name	ADVIA® Chemistry Systems Creatinine_2	ADVIA® Chemistry Systems Enzymatic Creatinine
Common name	Creatinine Test System	Creatinine Test System
510(k) Number	k973993	k991576
Manufacturer	Siemens Medical Solutions Diagnostics (formerly Bayer HealthCare LLC)	Siemens Medical Solutions Diagnostics (formerly Bayer HealthCare LLC)

Device Description:

The ADVIA Chemistry Enzymatic Creatinine_2 is used for the *in vitro* quantitative determination of creatinine in human serum, plasma and urine on the ADVIA®

Chemistry Systems. The proposed labeling indicates the ADVIA Chemistry Enzymatic Creatinine_2 reagents can be used on the ADVIA Chemistry 1200 / 1650 / 1800 / 2400 Systems.

The principle of the method is based on the enzymatic method employing creatininase, creatinase, sarcosine oxidase, horseradish peroxidase and N-(3-sulfopropyl)-3-methoxy-5-methylaniline (HMMPS) as the color agent. When a sample is mixed with Reagent 1 and Reagent 2, creatinine in the sample is converted to creatine by the action of creatininase. The creatine formed is hydrolyzed by creatinase to produce sarcosine and urea. The sarcosine is then decomposed by sarcosine oxidase to form glycine, formaldehyde and hydrogen peroxide. In the presence of peroxidase (POD), the hydrogen peroxide formed yields a blue pigment by quantitative oxidative condensation with N-(3-sulfopropyl)-3-methoxy-5-methylaniline (HMMPS) and 4-aminoantipyrine. The creatinine concentration is obtained by measuring the absorbance of blue color. The increase in optical absorbance is determined as an endpoint assay, which is proportional to the concentration of creatinine in the sample.

Statement of Intended Use:

The ADVIA Chemistry Enzymatic Creatinine_2 assay is for *in vitro* diagnostic use in the quantitative determination of creatinine in human serum, plasma or urine on the ADVIA® Chemistry Systems. Such measurements are used in the diagnosis and treatment of renal disease, and in monitoring renal dialysis.

Comparison to the Predicate Device:

Similarities

	ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) ***(new device)***	ADVIA Chemistry Creatinine_2 (CREA_2) ***(predicate device)***	ADVIA Chemistry Enzymatic Creatinine (CREA_E) ***(predicate device)***
Intended Use	Quantitative determination of creatinine	Quantitative determination of creatinine	Quantitative determination of creatinine
Specimen Type	Human serum or plasma (lithium heparin / K_2EDTA) or urine	Human serum or plasma (lithium heparin) or urine	Human serum or plasma (lithium heparin)
Calibration	Single point	Single point	Single point
Expected Values Serum/plasma	*Males: 0.6 – 1.1 mg/dL *Females: 0.5 – 0.8 mg/dL	Males: 0.7 – 1.3 mg/dL Females: 0.5 – 1.1 mg/dL	**Males: 0.9 – 1.3 mg/dL **Females: 0.6 – 1.1 mg/dL
Expected Values Urine	*Males: 800 – 2000 mg/day *Females: 600 – 1800 mg/day	*Males: 800 – 2000 mg/day *Females: 600 – 1800 mg/day	Not Applicable

*Tietz NW. *Clinical Guide to Laboratory Tests, 4th Edition*
** Tietz NW. *Clinical Guide to Laboratory Tests, 3rd Edition*

Differences

	ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) ***(new device)***	ADVIA Chemistry Creatinine_2 (CREA_2) ***(predicate device)***	ADVIA Chemistry Enzymatic Creatinine (CREA_E) ***(predicate device)***
Principle	Enzymatic (Creatininase)	Jaffe, alkaline picrate, kinetic with blank rate correction	Enzymatic (Creatinine Deiminase / GLDH)
Reaction Type	Colorimetric Endpoint	Colorimetric Rate	Colorimetric Rate
Reagents	Two liquid reagents, ready to use	Two liquid reagents, ready to use	Two lyophilized reagents, requiring reconstitution
Standardization	ID-MS (SRM 967)	HPLC candidate reference method	HPLC candidate reference method

Performance:

Substantial equivalence was demonstrated by testing several performance characteristics including imprecision, method comparison, interfering substances, serum/plasma equivalency, and analytical range. The following tables summarize the precision (total), interfering substances, analytical range, and method comparison results.

All of the evaluation studies gave acceptable results compared to the predicate devices. These studies support that the ADVIA Chemistry Enzymatic Creatinine_2 assay is substantially equivalent to the ADVIA Chemistry Creatinine_2 assay and the ADVIA Chemistry Enzymatic Creatinine assay that are currently marketed.

Imprecision (Serum)

ADVIA Chemistry Enzymatic Creatinine_2						**ADVIA Chemistry Creatinine_2**		**ADVIA Chemistry Enzymatic Creatinine**	
ADVIA 1650		ADVIA 2400		ADVIA 1200		ADVIA 1650		ADVIA 1650	
Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)
1.29	1.1	1.28		1.29	1.1	--	--	--	--
1.76	0.9	1.75	0.8	1.73	1.1	1.5	5.7	0.9	6.4
3.07	1.1	3.06	0.9	3.04	0.9	--	--	6.1	2.3
8.80	0.6	8.81	1.4	8.79	0.9	8.4	3.4	9.5	2.0

Imprecision (Urine)

ADVIA Chemistry Enzymatic Creatinine_2						**ADVIA Chemistry Creatinine_2**					
ADVIA 1650		ADVIA 2400		ADVIA 1200		ADVIA 1650		ADVIA 1200		ADVIA 2400	
Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)	Level (mg/dL)	Total CV (%)
41.56	1.3	41.13	1.0	42.34	1.0	--	--	--	--	--	--
77.27	1.0	77.54	0.9	79.78	1.1	81.5	4.3	79.7	2.1	80.7	2.1
130.59	0.9	131.33	0.9	133.09	1.0	202.7	1.8	182.5	1.9	199.7	1.4

Correlation (y = ADVIA Chemistry Enzymatic Creatinine_2, x = comparison system)

Specimen type, System (y)	Comparison System (x)	N	Regression Equation	Sy.x (mg/dL)	r	Sample Range (mg/dL)
Serum, ADVIA 1200	ADVIA 1200 Creatinine_2	60	Y = 1.017x + 0.03	0.07	1.000	0.3 – 12.3
Serum, ADVIA 1200	ADVIA 1200 Enzymatic Creatinine	28	Y = 0.933x + 0.11	0.14	1.000	0.5 - 25.6
Serum, ADVIA 1650	ADVIA 1650 Creatinine_2	60	Y = 1.018x - 0.04	0.13	1.000	0.3 – 11.9
Serum, ADVIA 1650	ADVIA 1650 Enzymatic Creatinine	42	Y = 0.957x + 0.04	0.12	1.000	0.6 - 25.7
Serum, ADVIA 2400	ADVIA 2400 Creatinine_2	60	Y = 1.026x – 0.03	0.13	1.000	0.3 – 12.1
Serum, ADVIA 2400	ADVIA 2400 Enzymatic Creatinine	42	Y = 0.954x + 0.01	0.07	1.000	0.6 - 25.4
Urine, ADVIA 1200	ADVIA 1200 Creatinine_2	46	Y = 1.042x + 0.41	1.80	1.000	20.0 – 238.1
Urine, ADVIA 1650	ADVIA 1650 Creatinine_2	49	Y = 1.019x – 0.99	1.88	1.000	17.8 – 239.4
Urine, ADVIA 2400	ADVIA 2400 Creatinine_2	44	Y = 1.025x + 2.47	2.99	0.999	18.9 - 218.1

Interfering Substances (Enzymatic Creatinine_2)

Interfering Substance	Conc. (mg/dL)	Creatinine conc. (mg/dL)			Effect (% change)		
		ADVIA 1200	ADVIA 1650	ADVIA 2400	ADVIA 1200	ADVIA 1650	ADVIA 2400
Hemoglobin	500	0.94	0.92	0.91	7.5	6.6	6.6
	1000	3.08	3.06	3.00	-2.8	-3.8	- 2.2
Lipids (Intralipid)	1000	0.91	0.88	0.87	6.6	-5.7	-1.2
	1000	3.09	3.03	2.97	-2.4	-5.3	-4.2
Bilirubin, free	30.0	0.96	1.01	0.94	-8.9	-7.4	-9.6
	22.5	3.05	3.05	3.22	-6.6	-6.1	-9.8
Bilirubin, conjugated	30.0	0.92	0.90	0.91	-2.7	-5.6	-5.5
	30.0	2.96	2.97	2.94	-4.6	-5.4	-6.0

Analytical Range – Serum/Plasma

Platform	ADVIA Chemistry Enzymatic Creatinine_2
ADVIA 1650	0.1 - 30.0 mg/dL
ADVIA 2400	0.1 - 30.0 mg/dL
ADVIA 1200	0.1 - 30.0 mg/dL

Analytical Range – Urine

Platform	ADVIA Chemistry Enzymatic Creatinine_2
ADVIA 1650	1.0 - 245 mg/dL
ADVIA 2400	1.0 - 245 mg/dL
ADVIA 1200	1.0 - 245 mg/dL

Conclusions:

The ADVIA Chemistry Enzymatic Creatinine_2 assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Siemens Diagnostics (formerly Bayer HealthCare LLC) ADVIA Chemistry Creatinine_2 (k973993) and Enzymatic Creatinine methods (k991576).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 3 2007

Siemens Medical Solutions Diagnostics
c/o Mr. Philip Liu, Manager, Regulatory Affairs & Compliance
511 Benedict Avenue
Tarrytown, NY 10591

Re: k070727
Trade Name: Advia Chemistry Enzymatic Creatinine-2
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY
Dated: July 20, 2007
Received: July 23, 2007

Dear Mr. Liu:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
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Enclosure

Indications for Use

510(k) Number (if known): K070727

Device Name: ADVIA CHEMISTRY ENZYMATIC CREATININE_2

Indications For Use:

For *in vitro* diagnostic use in the quantitative determination of creatinine in human serum, plasma, and urine on the ADVIA Chemistry Systems. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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