DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 15, 2016

SIEMENS HEALTHCARE DIAGNOSTICS, INC.
LAURA DUGGAN, PH.D.
REGULATORY TECHNICAL SPECIALIST
500 GBC DRIVE, PO BOX 6101 MS 514
NEWARK DE 19711

Re: K161494
Trade/Device Name: Atellica CH Creatinine_2 (Crea_2); Atellica™ CH Chemistry Calibrator (CHEM CAL)
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: CGX, JIT
Dated: September 26, 2016
Received: September 27, 2016

Dear Dr. Laura Duggan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k161494

Device Name

Atellica CH Creatinine_2 (Crea_2);Atellica™ CH Chemistry Calibrator (CHEM CAL)

Indications for Use *(Describe)*

The Atellica™ CH Creatinine_2 (Crea_2) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin), and urine using the Atellica™ CH Analyzer. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

The Atellica™ CH Chemistry Calibrator (CHEM CAL) is for in vitro diagnostic use in calibrating the Crea_2 assay using the Atellica™ CH Analyzer.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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10. 510(K) SUMMARY

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

ASSIGNED 510(K) NUMBER

The assigned 510(k) number is k161494.

APPLICANT AND DATE

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November 11, 2016

MANUFACTURER

Siemens Healthcare Diagnostics Inc.
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Registration Number: 2432235

REGULATORY INFORMATION

Regulatory Submission for the Atellica™ CH Creatinine_2 (Crea_2) and Atellica™ CH Chemistry Calibrator (CHEM CAL)

Common Name:	Alkaline Picrate, Colorimetry, Creatinine	Calibrator, Secondary
Proprietary Name:	Atellica CH Creatinine_2 (Crea_2)	Atellica CH Chemistry Calibrator (CHEM CAL)
Classification Name:	Creatinine Test System	Calibrator
Regulation Number:	21CFR862.1225	21CFR862.1150
Classification:	Class II	Class II
Product Code:	CGX	JIT
Panel:	Clinical Chemistry	Clinical Chemistry
Predicate Device:	ADVIA Chemistry Enzymatic	ADVIA Chemistry Calibrator

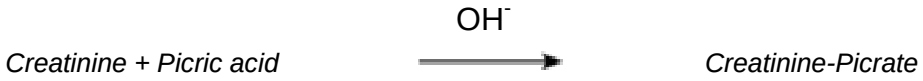
	Creatinine_2 (ECRE_2) (k070727)	(k050374)

DEVICE DESCRIPTION

ATELLICA CH CREATININE_2 (CREA_2)

The Atellica CH Creatinine_2 (Crea_2) assay is based on the reaction of picric acid with creatinine in an alkaline medium as described in the original procedure of Jaffe. Creatinine reacts with picric acid in an alkaline medium to produce a red-colored creatinine-picrate complex. The rate of complex formation is measured at 505/571 nm and is proportional to the creatinine concentration. The Atellica CH Creatinine_2 (Crea_2) assay is a modification of the Jaffe method using rate blanking and intercept correction. Rate blanking is used to minimize bilirubin interference. Also, because non-specific serum/plasma protein interactions with this reagent have been found to produce a positive bias of approximately 0.3 mg/dL (26.5 µmol/L), serum/plasma measurements are automatically corrected by subtracting 0.3 mg/dL (26.5 µmol/L) from each result.

Reaction Equation



Serum, lithium heparin plasma and urine specimens may be used. The reagent is stored unopened at 2 – 8 °C and is stable for use on system for 17 days. Calibration is performed every 60 days for a reagent lot or every 6 days for an individual pack.

ATELLICA CH CHEMISTRY CALIBRATOR (CHEM CAL)

The Atellica CH Chemistry Calibrator (CHEM CAL) is a 1 level lyophilized calibrator product prepared from bovine serum base product. The product is stored at 2 – 8 °C. The Atellica CH Chemistry Calibrator is stable for 48 hours at 2 – 8 °C after being opened, rehydrated and securely recapped.

INTENDED USE/INDICATIONS FOR USE

ATELLICA CH CREATININE_2 (CREA_2)

The Atellica™ CH Creatinine_2 (Crea_2) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin), and urine using the Atellica™ CH Analyzer. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

ATELLICA CH CHEMISTRY CALIBRATOR (CHEM CAL)

The Atellica™ CH Chemistry Calibrator (CHEM CAL) is for *in vitro* diagnostic use in calibrating the Crea_2 assay using the Atellica™ CH Analyzer.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Below is a features comparison for the Atellica CH Creatinine_2 (Crea_2) assay and the Chemistry calibrator (CHEM CAL) vs. their predicates:

Feature	**Predicate Device:** ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) (k070727)	**New Device:** Atellica CH Creatinine_2 (Crea_2)
Intended Use :	For in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin and K2EDTA), and urine on ADVIA Chemistry systems. .	The Atellica™ CH Creatinine_2 (Crea_2) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin), and urine using the Atellica™ CH Analyzer.
Indications for Use:	Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis	Same
Device Technology:	Enzymatic reaction of Fossati, Prencipe, and Berti	Reaction of picric acid with creatinine in an alkaline medium as described in the original procedure of Jaffe.
Sample Type:	Serum, Lithium Heparin	Serum, Lithium Heparin

	plasma, K_2-EDTA plasma and urine	plasma, and urine
Reference Interval:	Serum/Plasma Males 0.6 – 1.1 mg/dL Females 0.5 – 0.8 mg/dL Urine Males 800 – 2000 mg/day Females 600 – 1800 mg/day	Serum/plasma Males 0.70-1.30 mg/dL Females 0.55 -1.02 mg/dL Urine : Males 950 – 2490 mg/day Females 600 – 1800 mg/day
Standardization:	SRM967	IDMS Reference Method
Calibration Frequency:	60 days	Same
Analytical Measuring Interval:	Serum/Plasma: 0.10 – 30.00 mg/dL Urine: 1.0 – 245.00 mg/dL	Serum and plasma: 0.15–30.00 mg/dL Urine: 3.00–245.00 mg/dL
Interferences:	Bilirubin (Unconjugated) – 30 mg/dL Bilirubin (Conjugated) – 30 md/dL Lipemia (Intralipid®) – 1000 mg/dL Hemoglobin – 500 mg/dL	Bilirubin (Unconjugated) – 10 mg/dL Bilirubin (Conjugated) – 20 md/dL Lipemia (Intralipid®) – 500 mg/dL Hemoglobin – 500 mg/dL
Calibrators:	ADVIA Chemistry Calibrator (k050374)	Atellica CH Chemistry Calibrator

Feature	**Predicate Device:** ADVIA Chemistry Calibrator (k050374)	**New Device:** Atellica CH Chemistry Calibrator (CHEM CAL)
Intended Use :	For in vitro diagnostic use in the calibration of chemistry	The Atellica™ CH Chemistry Calibrator (CHEM CAL) is for

	assays on ADVIA® Chemistry systems.	*in vitro* diagnostic use in calibrating the Crea_2 assay using the Atellica™ CH Analyzer.
Calibrator Matrix:	Bovine Serum Base	Same
Calibrator Form:	Lyophilized	Same
Number of Calibrator Levels:	One	Same

SUMMARY OF PERFORMANCE TESTING

Assay performance comparison results for the Atellica CH Creatinine_2 (Crea_2) with the Atellica CH Chemistry Calibrator (CHEM CAL) were obtained by processing the appropriate body fluids. Summary statistics for each are provided. These data demonstrate substantial equivalency of the Atellica CH Creatinine_2 (Crea_2) and the Atellica CH Chemistry Calibrator (CHEM CAL) versus the predicate devices. The following data represent typical assay performance.

DETECTION LIMIT

The Limit of Blank (LoB) and Limit of Detection (LoD) were evaluated in accordance with CLSI EP17-A2 Protocols for Determination of Limits of Detection and Limits of Quantitation: Approved Guideline.

Assessment of LoB was the 95th percentile of all values (sorted from lowest to highest), using non-parametric approach.

LoB Rank Position = 0.5 +0.95*B, where B=total reps=60; Rank = 57.5

Atellica CH Creatinine_2 (Crea_2) - Limit of Detection Results		
Limit	Protocol	Result
LoB	4 samples with no analyte were tested (N=5) for 3 days, one run per day, 3 reagent lots	0.03 mg/dL serum 0.35 mg/dL urine

LoD	4 low analyte samples were tested (N=5) for 3 days, one run per day, 3 reagent lots	0.08 mg/dL serum 0.51 mg/dL urine

The nonparametric approach described in EP17-A2 was followed to determine the Limit of Detection.

LOQ

The Limit of Quantitation (LoQ) for serum was determined as described in CLSI Document EP17-A2. Total Error is calculated using: TE = bias + 2 * SD.

Five replicates of ten low samples were processed on three reagent lots for three days on five calibrations per day, on one instrument for a total of 75 measurements per reagent lot per sample. For serum, the measured LoQ was 0.13 mg/dL in support of the LoQ claim of 0.15 mg/dL for serum and plasma samples. For urine, the measured LoQ was 2.57 mg/dL in support of the LoQ claim of 3.00 mg/dL for urine samples. The LoQ claims for serum and urine are each based a total of 2250 determinations with a total error goal of ≤ ±0.1 mg/dL for serum specimens and ≤ ±1.5 mg/dL for urine specimens.

LINEARITY STUDY

Linearity was evaluated with 12 samples which spanned the assay measuring interval for serum and plasma specimens and 10 samples which spanned the assay measuring interval for urine specimens. Each was prepared by mixing high and low concentration samples across the measurement interval as described in CLSI Evaluation of the Linearity of Quantitative Measurement Procedure (EP06-A). The high sample was prepared by spiking native serum or urine pools with purified creatinine. Low pools were created by diluting serum and urine samples with a 6% BSA or 0.9% saline solution respectively. Five replicates were measured for each sample. The mean of these replicates was used for the calculations.

The assay was considered linear across the measuring interval if the p values of nonlinear terms in the quadratic and cubic fit equations are nonsignificant ($p \leq 0.05$). If the p-value is > 0.05, then the allowable bias is ≤ 5% or 0.15 mg/dL, whichever is greater.

PRECISION STUDIES

Precision testing was performed in accordance with CLSI EP05-A3 Evaluation of Precision Performance of Quantitative Measurement Methods: Approved Guideline –

Third Edition. Precision was tested n = 2 replicates, two times a day for at least 20 days for a total of 80 replicates with controls, serum and plasma pools on one instrument. Analysis of variance (ANOVA) was used to evaluate the data consistent with the recommendations of EP05-A3. The data are summarized in the following table.

			Repeatability		Within-Lab Precision	
Sample Type	n	Mean mg/dL (µmol/L)	SD[a] mg/dL (µmol/L)	CV[b] (%)	SD[a] mg/dL (µmol/L)	CV[b] (%)
Serum	80	0.38 (34)	0.01 (0.5)	1.7	0.010 (0.9)	2.8
Plasma Pool	80	0.66 (58)	0.01 (0.7)	1.2	0.018 (1.6)	2.8
Serum Pool	80	1.16 (103)	0.01 (0.9)	0.8	0.017 (1.5)	1.5
Serum QC	80	1.97 (174)	0.02 (1.6)	0.9	0.024 (2.1)	1.2
Serum QC	80	6.35 (561)	0.04 (3.7)	0.7	0.062 (5.5)	1.0
Serum Pool	80	19.31 (1707)	0.04 (3.4)	0.2	0.117 (10.3)	0.6
Serum Pool	80	26.00 (2298)	0.05 (4.7)	0.2	0.145 (12.8)	0.6
Urine QC	80	59.62 (5270)	0.15 (13.5)	0.3	0.376 (33.2)	0.6
Urine QC	80	133.31 (11785)	0.33 (29.4)	0.2	0.961 (85.0)	0.7
Urine	80	188.61 (16673)	0.52 (46.1)	0.3	1.779 (157.3)	0.9

[a] SD = standard deviation
[b] CV = coefficient of variation

INTERFERENCES

CLSI EP7-A2 was followed for the interference testing. The interference study was conducted using a “paired difference worst case scenario” approach where these compounds were spiked into fresh sample pools containing either low or high levels of measurand in serum and urine pools.

Bias is the difference in the results between the control sample (without the interferent) and the test sample (contains the interferent) expressed in percent. Bias exceeding 10% is considered interference. Dilution studies were conducted to determine the level at which the spiked substance no longer displayed significant interference. Dilution studies were conducted at two analyte concentrations, if both sample pools show significant interference. This study was conducted as needed for both serum pools.

Approximate Concentration (within 15%) of Analytes in Test Pools			
Analyte	Matrix	Low	High
Creatinine	Serum	1.50 mg/dL	5.00 mg/dL
Creatinine	Urine	40.00 mg/dL	180.00 mg/dL

No interference was detected at the following analyte concentrations.

Compounds tested for interference in Serum

Substance	Substance Test Concentration Common Unit (SI Unit)
Glucose	182 mg/dL (10.1 mmol/L)
Ascorbate	3.0 mg/dL (171 mmol/L)
Total Protein	11.7 g/dL (117 g/L)
Cefoxitin	3.75 mg/dL (88 mmol/L)
Cephalexin	25 mg/dL (720 mmol/L)
Pyruvate	7.5 mg/dL (852 µmol/L)
Acetoacetate	20 mg/dL (1959 µmol/L)
Potassium Oxalate	500 mg/dL (30 mol/L)
Dopamine (LevaDopa)	75 mg/dL (3.8 mol/L)
Albumin	6000 mg/dL (60 g/L)
Amikacin	8 mg/dL (137 µmol/L)
Caffiene	6 mg/dL (308 µmol/L))
Carbamezepine	3 mg/dL (127 µmol/L)
Cephradine	25 mg/dL (769 µmol/L)
Chloramphenicol	5 mg/dL (155 µmol/L)
Chlordiazepoxide	1 mg/dL (33.3 µmol/L)
Cimetidine	2 mg/dL (2652 µmol/L)
Dextran	6000 mg/dL (1500 µmol/L)
Diazepam	0.51 mg/dL (18 µmol/L)
Digoxin	6.1 ng/mL (7.8 nmol/L)
EDTA	200 mg/dL (2 g/L)
Erythromycin	6 mg/dL (81.6 µmol/L)
Ethanol	400 mg/dL (86.8 mmol/L)
Ethosuximide	25 mg/dL (1770 µmol/L)
Furosemide	6 mg/dL (181 µmol/L)
Gentamicin	1 mg/dL (21 µmol/L)
IgG	5000 mg/dL (5000 g/L)
Isopropanol	1 g/dL (166 mmol/L)
Lidocaine	1.2 mg/dL (51.2 µmol/L)
Nicotine	0.1 mg/dL (6.2 µmol/L)
Nortriptyline	1000 ng/mL (3797 µmol/L)
Penicillin G(1654)	25 U/mL (25000 U/L)
Pentobarbital	8 mg/dL (354 µmol/L)
Phenobarbitol	10 mg/dL (431 µmol/L)
Phenytoin	5 mg/dL (198 µmol/L)
Primidone	4 mg/dL (183 µmol/L)
Propoxyphene	0.16 mg/dL (4.91 µmol/L)
Sodium Fluoride	400 mg/dL (4 g/L)
Theophylline	4 mg/dL (222 µmol/L)
Triglyceride	2500 mg/dL (17 mmol/L
Urea	500 mg/dL (28.3 mmol/L)
Uric acid	20 mg/dL (1190 µmol/L)
Valproic Acid	50 mg/dL (3467 µmol/L)
Vancomycin	10 mg/dL (69 µmol/L)

Compounds tested for interference in Urine

Substance	Substance Test Concentration Common Unit (SI Unit)
6N HCL	0.01% HCl
Boric Acid	1% w/v
pH 4	----
pH 9	----
Ascorbate	3.0 mg/dL (171 mmol/L)
Glucose	2000 mg/dL (111 mmol/L)
Conjugated Bilirubin	50 mg/dL (855 µmol/L)
Hemoglobin	100 mg/dL (62.2 µmol/L)
Acetaminophen	200 mg/dL (1324 µmol/L)
N-Acetyl cysteine	2 mg/dL (123 mmol/L)
Ibuprofen	500 mg/dL (24 mol/L)
Acetic Acid	25 mL/24 hr collection
6N Nitric Acid	0.60%
Ethanol	1 g/dL (217 mmol/L)
Gamma Globulin	0.5 g/dL (5 g/L)
Human Serum Albumin	0.5 g/dL (5 g/L)
Oxalic Acid	0.1 g/dL (110 mmol/L)
Sodium carbonate	5 g/24 hr collection

METHOD COMPARISON

The predicate device selected for the method comparison study was the ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) (k070727). Remnant de-identified

samples were tested. No patient history information was obtained on these samples. Inclusion/exclusion data criteria are not applicable. The study included native and spiked samples to properly span the assay intervals.

These studies were conducted internally by Siemens Healthcare Diagnostic Inc. R&D organization personnel. The personnel conducting the study were laboratory technicians with training similar to personnel who would conduct the tests in a hospital laboratory setting. They were trained on the operation of both the device and the predicate device. A split sample method comparison, following EP09-A3, demonstrated good agreement between the Atellica CH Creatinine_2 (Crea_2) and the predicate ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) assay with patient samples.

The table below also summarizes the data for comparison between Isotope Dilution Mass Spectrometry (IDMS) and the Atellica Creatinine_2 (Crea_2) assay. These data demonstrate good agreement with IDMS.

The results across the full assay intervals were analyzed using weighted Deming regression. One replicate of each sample was tested and used in the analysis.

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sample Range
Serum	ADVIA Ecre_2	140	0.999	y = 0.98x + 0.00 mg/dL	0.12–28.89 mg/dL
Urine	ADVIA Ecre_2	109	0.999	y = 0.95x +0.07 mg/dL	3.57 – 238.85 mg/dL
Serum	Isotope Dilution Mass Spectrometry (IDMS)	49	0.999	y = 0.96x + 0.05 mg/dL	0.41 – 32.09 mg/dL

MATRIX EQUIVALENCY

Serum and lithium heparin plasma equivalency was demonstrated by testing fifty eight matched samples. Some samples were spiked with creatinine to obtain samples spanning the assay measuring intervals. The table below summarizes the weighted Deming linear regression statistics. One replicate of each sample was tested and used in the analysis.

Specimen Type	Comparison Assay (x)	N	r	Regression Equation	Sample Range
Plasma (Lithium heparin)	Atellica CH Crea_2 – Serum	58	1.000	y = 1.00x – 0.01 mg/dL	0.68 – 24.87 mg/dL

REFERENCE INTERVAL

Reference intervals for healthy adults were verified on the Atellica CH Analyzer in accordance with CLSI Document EP28-A3c. As with all in vitro diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.

Group	Specimen type	Reference Interval common unit (SI unit)
Adult males	Serum/plasma[1]	0.70 - 1.30 mg/dL (62 - 115 µmol/L)
Adult females	Serum/plasma[2]	0.55 - 1.02 mg/dL (49 - 90 µmol/L)
Adult males	Urine[3]	950 - 2490 mg/day (8.4 - 22.0 mmol/day)
Adult females	Urine[4]	600 - 1800 mg/day (5.3 - 15.9 mmol/day)

1. Burtis CA, Ashwood ER, eds. *Tietz Fundamentals of Clinical Chemistry.* 5th ed. Philadelphia, PA: WB Saunders Co; 2001:23-25, 422.
2. Ceriotti F, Boyd JC, Klein G, *et al*. Reference intervals for serum creatinine concentrations: assessment of available data for global application. *Clin Chem.* 2008;54(3):559-566.
3. Junge W, Wilke B, Halabi A, Klein G. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and a modified Jaffé method. *Clin Chim Acta.* 2004;344(1-2):137-48.
4. Burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry.* 3rd ed. Philadelphia, PA: WB Saunders Co; 1999:1809.

CONCLUSION

The Atellica CH Creatinine_2 (Crea_2) and the Atellica CH Chemistry Calibrator (CHEM CAL) are substantially equivalent to the ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) (k070727) and the ADVIA Chemistry Calibrator (k050374) in principle and performance based on the similarity of device designs and function demonstrated through method comparison and other performance attributes.