DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

RADIOMETER AMERICA INC.
KAREN BANG JAKOBSEN
REGULATORY AFFAIRS SPECIALIST
250 S. KRAEMER BLVD
BREA, CA 92821

January 28, 2016

Re: K153712
Trade/Device Name: VK-3 Verification Kit; VK-4 Verification Kit; VK-R5 Verification Kit; VK-R7 Verification Kit; VK-Crea Verification Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Multi-analyte controls, all kinds (assayed)
Regulatory Class: I, reserved
Product Code: JJY
Dated: December 21, 2015
Received: December 24, 2015

Dear Karen Bang Jakobsen:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

---------REMOVE THIS PAGE WHEN PRINTING OR EMAILING TO SPONSOR---------

510(k) Number: K133410

Digital Signature Concurrence Table	
Reviewer Sign-Off	Sheila Connors/NG
Branch Chief Sign-Off	Yung Chan
Division Sign-Off	

Template Name: OIR Letter Generator v1.10 - Letter type: SE

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)*

k153712

Device Name

VK-3 Verification Kit, VK-4 Verification Kit, VK-R5 Verification Kit, VK-R7 Verification Kit and VK-Crea Verification Kit

Indications for Use *(Describe)*

For in vitro diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary k153712

1 Administative information

Submitter

Company Name:	Radiometer America Inc.
ER Number:	3010420736
Address:	250 S. Kraemer Blvd Brea, CA 92821 (USA)
Phone:	800-736-0600
Fax:	800-736-0601

Contact Person

Name:	Karen Bang Jakobsen
Function:	Regulatory Affairs Specialist
E-mail:	Karen.bang.jakobsen@radiometer.dk
Phone:	+45 3827 3827
Fax:	+45 3827 2727

Date prepared

Date: December 21, 2015

Device Information

Device Name: VK-3 Verification Kit
VK-4 Verification Kit
VK-R5 Verification Kit
VK-R7 Verification Kit
VK-Crea Verification Kit

Common Name: Calibration Verification Kit

Classification:

Classification name	CFR Section	Device Class	Product Code
Multi-analyte controls, all kinds (assayed)	862.1660	I, reserved	JJY

2 Device Description

VK-3 Verification Kit

VK-3 Verification Kit is a calibration verification kit consisting of the following 5 quality control solutions:

- Hematocrit and Metabolite QUALICHECK Level 1, S7170 (K150226)
- Hematocrit and Metabolite QUALICHECK Level 2, S7180 (K150226)
- Range+ QUALICHECK Level 1, S7930 (K130236)
- Range+ QUALICHECK Level 2, S7940 (K130236)
- Range+ QUALICHECK Level 3, S7950 (K130236)

These quality control solutions have been 510(k) cleared (K150226 and K130236) with an intended use which did not include calibration verification. Production of this kit consists solely in repackaging and relabeling of the already cleared products.

Each kit consists of 4 ampoules of each constituent quality control solution. One ampoule contains 2 mL of solution.

The Hematocrit and Metabolite QUALICHECK quality control solutions are aqueous solutions containing organic buffer, acid, salts, metabolites, and a preservative.
The Range+ QUALICHECK quality control solutions are aqueous solutions containing biological buffers, salts, glucose, lactate, dyes and a preservative, and are equilibrated with carbon dioxide and oxygen.

VK-4 Verification Kit

VK-4 Verification Kit is a calibration verification kit consisting of the following 4 quality control solutions:

- Qualicheck 5+ Level 1, S7730 (K980135)
- Qualicheck 5+ Level 2, S7740 (K980135)
- Qualicheck 5+ Level 3, S7750 (K980135)
- Qualicheck 5+ Level 4, S7760 (K980135)

These quality control solutions have been 510(k) cleared (K980135) with an intended use which did not include calibration verification. Production of this kit consists solely in repackaging and relabeling of the already cleared products.

Each kit consists of 4 ampoules of each constituent quality control solution. One ampoule contains 2 mL of solution.

The quality control solutions are aqueous solutions containing biological buffers, salts, glucose, lactate, dyes and a preservative, and are equilibrated with carbon dioxide and oxygen.

VK-R5 Verification Kit

VK-R5 Verification Kit is a calibration verification kit consisting of the following 4 quality control solutions:

- Range+ QUALICHECK Level 1, S7930 (K130236)
- Range+ QUALICHECK Level 2, S7940 (K130236)
- Range+ QUALICHECK Level 3, S7950 (K130236)
- Qualicheck 5+, Level 3, S7750, (K980135)

These quality control solutions have been 510(k) cleared (K130236 and K980135) with an intended use which did not include calibration verification. Production of this kit consists solely in repackaging and relabeling of the already cleared products.

Each kit consists of 4 ampoules of each constituent quality control solution. One ampoule contains 2 mL of solution.

The quality control solutions are aqueous solutions containing biological buffers, salts, glucose, lactate, dyes and a preservative, and are equilibrated with carbon dioxide and oxygen.

VK-R7 Verification Kit

VK-R7 Verification Kit is a calibration verification kit consisting of the following 4 quality control solutions:

- Range+ QUALICHECK Level 1, S7930 (K130236)
- Range+ QUALICHECK Level 2, S7940 (K130236)
- Range+ QUALICHECK Level 3, S7950 (K130236)
- High Metabolite QUALICHECK Level 1, S7570 (K130415)

These quality control solutions have been 510(k) cleared (K130236 and K130415) with an intended use which did not include calibration verification. Production of this kit consists solely in repackaging and relabeling of the already cleared products.

Each kit consists of 4 ampoules of each constituent quality control solution. One ampoule contains 2 mL of solution.

The Range+ QUALICHECK quality control solutions are aqueous solutions containing biological buffers, salts, glucose, lactate, dyes and a preservative, and are equilibrated with carbon dioxide and oxygen.
The High Metabolite QUALICHECK quality control solutions are aqueous solutions containing biological buffers, salts, metabolites and a preservative

VK-Crea Verification Kit

VK-Crea Verification Kit is a calibration verification kit consisting of the following 4 quality control solutions:

- AutoCheck6+ Level 1, S7835 (K051928)
- AutoCheck6+ Level 2, S7845 (K051928)
- AutoCheck6+ Level 3, S7855 (K051928)
- Cleaning Met II Solution, S8377 (K051968)

These quality control solutions have been 510(k) cleared (K051928) and (K051968) with an intended use which did not include calibration verification. Production of this kit consists solely in repackaging and relabeling of the already cleared products.

Each kit consists of 4 ampoules of each level of AutoCheck6+ and one bottle of Cleaning Met II Solution. Each AutoCheck6+ ampoule contains 0.7 mL solution. The Cleaning Met II Solution contains 100 mL solution.

The quality control solutions are aqueous solutions containing biological buffers, salts, metabolites, enzyme and a preservative. The AutoCheck6+ solutions also contain dyes and are equilibrated with carbon dioxide and oxygen.

3 Purpose of submission

To seek clearance of five calibration verification kits based on already cleared quality control solutions.

4 Intended Use/Indications for use

For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.

5 Predicate device

Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets (K091225)

6 Substantial Equivalence

All five Verification Kits are substantially equivalent in intended use, fundamental scientific technology, features, and characteristics to the predicate device:

510(k) Number; Name; Device Manufacturer:
K091225; Validate GC1 Calibration Verification/Linearity Test Set; Validate GC2 Calibration Verification/Linearity Test Set; Validate GC3 Calibration Verification/Linearity Test Set; Validate GC4 Calibration Verification/Linearity Test Set
Maine Standards Co.

VK-3 Verification Kit

Similarities		
Issue	**SE Device (VK-3 Verification Kit)**	**Predicate Device (K091225)**
Intended Use	For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.	Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.
Product code	JJY (Multi-analyte controls, all kinds (assayed))	JJY (Multi-analyte controls, all kinds (assayed))
Form	Liquid	Liquid
Matrix	Aqueous	GC1: Human serum GC2: Aqueous GC3: Human serum GC4: Human serum
Traceability	IUPAC pH scale, NIST SRM, IECC	NIST SRM, primary analytical standards

Similarities		
Issue	**SE Device (VK-3 Verification Kit)**	**Predicate Device (K091225)**
Measurands	pH, *p*CO2, *p*O2, *c*K+, *c*Na+, *c*Ca2+, *c*Cl–, *c*Glu and Hct	GC1: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA) GC2: Ammonia (NH3), Carbon Dioxide (CO_2), Ethanol (ETOH), and Iron (FE) GC3: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) GC4: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL)
Storage	2 – 8 °C	2 – 8 °C

Differences		
Issue	**SE Device (VK-3 Verification Kit)**	**Predicate Device (K091225)**
Shelf life	24 months (as a maximum, depending on the remaining shelf life of the oldest component)	12 months
Open vial stability	N/A, shall be used immediately	12 months
Levels	3 (2 levels for Hct)	6

VK-4 Verification Kit

Similarities		
Issue	**SE Device (VK-4 Verification Kit)**	**Predicate Device (K091225)**
Intended Use	For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.	Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.
Product code	JJY (Multi-analyte controls, all kinds (assayed))	JJY (Multi-analyte controls, all kinds (assayed))
Form	Liquid	Liquid
Matrix	Aqueous	GC1: Human serum GC2: Aqueous GC3: Human serum GC4: Human serum
Traceability	IUPAC pH scale, NIST SRM	NIST SRM, primary analytical standards
Measurands	pH, *p*CO2, *p*O2	GC1: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA) GC2: Ammonia (NH3), Carbon Dioxide (CO_2), Ethanol (ETOH), and Iron (FE) GC3: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) GC4: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL)

Differences		
Issue	**SE Device (VK-4 Verification Kit)**	**Predicate Device (K091225)**
Storage	2 – 25 °C	2 – 8 °C
Shelf life	24 months (as a maximum, depending on the remaining shelf life of the oldest component)	12 months
Open vial stability	N/A, shall be used immediately	12 months
Levels	4	6

VK-R5 Verification Kit

Similarities		
Issue	**SE Device (VK-R5 Verification Kit)**	**Predicate Device (K091225)**
Intended Use	For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.	Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.
Product code	JJY (Multi-analyte controls, all kinds (assayed))	JJY (Multi-analyte controls, all kinds (assayed))
Form	Liquid	Liquid
Matrix	Aqueous	GC1: Human serum GC2: Aqueous GC3: Human serum GC4: Human serum
Traceability	IUPAC pH scale, NIST SRM, IFCC, SIGMA	NIST SRM, primary analytical standards

Similarities		
Issue	**SE Device (VK-R5 Verification Kit)**	**Predicate Device (K091225)**
Measurands	pH, *p*CO2, *p*O2, *c*K+, *c*Na+, *c*Ca2+, *c*Cl–, *c*Glu, *c*Lac, *c*tHb, *s*O2, *F*O2Hb, *F*COHb, *F*MetHb, *F*HbF and *c*tBil	GC1: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA) GC2: Ammonia (NH3), Carbon Dioxide (CO_2), Ethanol (ETOH), and Iron (FE) GC3: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) GC4: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL)
Storage	2 – 8 °C	2 – 8 °C

Differences		
Issue	**SE Device (VK-R5 Verification Kit)**	**Predicate Device (K091225)**
Shelf life	24 months (as a maximum, depending on the remaining shelf life of the oldest component)	12 months
Open vial stability	N/A, shall be used immediately	12 months
Levels	3 (4 levels for Glu)	6

VK-R7 Verification Kit

Similarities		
Issue	**SE Device (VK-R7 Verification Kit)**	**Predicate Device (K091225)**
Intended Use	For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.	Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.
Product code	JJY (Multi-analyte controls, all kinds (assayed))	JJY (Multi-analyte controls, all kinds (assayed))
Form	Liquid	Liquid
Matrix	Aqueous	GC1: Human serum GC2: Aqueous GC3: Human serum GC4: Human serum
Traceability	IUPAC pH scale, NIST SRM, SIGMA, IFCC	NIST SRM, primary analytical standards
Measurands	pH, pCO2, pO2, cK+, cNa+, cCa2+, cCl−, cGlu, cLac, ctHb, sO2, FO2Hb, FCOHb, FMetHb, FHbF and ctBil	GC1: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA) GC2: Ammonia (NH3), Carbon Dioxide (CO_2), Ethanol (ETOH), and Iron (FE) GC3: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) GC4: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL)
Storage	2 – 8 °C	2 – 8 °C

Differences		
Issue	**SE Device (VK-R7 Verification Kit)**	**Predicate Device (K091225)**
Shelf life	24 months (as a maximum, depending on the remaining shelf life of the oldest component)	12 months
Open vial stability	N/A, shall be used immediately	12 months
Levels	3 (4 levels for pO2 and ctHb)	6

VK-Crea Verification Kit

Similarities		
Issue	**SE Device (VK-Crea Verification Kit)**	**Predicate Device (K091225)**
Intended Use	For *in vitro* diagnostic use. Verification Kits VK-3, VK-4, VK-R5, VK-R7 and VK-Crea are assayed quality control systems for calibration verification for the parameters and the analyzers listed in the insert specifying the control ranges.	Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.
Product code	JJY (Multi-analyte controls, all kinds (assayed))	JJY (Multi-analyte controls, all kinds (assayed))
Form	Liquid	Liquid
Matrix	Aqueous	GC1: Human serum GC2: Aqueous GC3: Human serum GC4: Human serum
Traceability	NIST SRM	NIST SRM, primary analytical standards

Similarities		
Issue	**SE Device (VK-Crea Verification Kit)**	**Predicate Device (K091225)**
Measurands	*c*Crea	GC1: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA) GC2: Ammonia (NH3), Carbon Dioxide (CO_2), Ethanol (ETOH), and Iron (FE) GC3: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) GC4: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL)
Storage	2 – 8 °C	2 – 8 °C
Shelf life	12 months (as a maximum, depending on the remaining shelf life of the oldest component)	12 months

Differences		
Issue	**SE Device (VK-Crea Verification Kit)**	**Predicate Device (K091225)**
Open vial stability	N/A, shall be used immediately	12 months
Levels	4	6

7 Performance Characteristics

7.1 Stability

The expiration date of a specific kit is defined as the earliest of the expiration dates for the individual components of the kit as specified in the labeling for the components. Since the stability is not affected by the repackaging, the stability is documented by reference to K150226, K130236, K980135, K130415, K051928 and K051968.

7.2 Storage

The storage conditions for the kits are the storage conditions for the most temperature sensitive component in the kits as specified in the labeling for the components. Storage conditions are 2 °C – 8 °C for VK-3, VK-R5, VK-R7 and VK-Crea. Storage conditions are 2 °C – 25 °C for VK-4. Since the stability is not affected by the repackaging, the stability and storage conditions are documented by reference to K150226, K130236, K980135, K130415, K051928 and K051968.

7.3 Traceability

The assigned values for each of the parameters are traceable to established international references as defined for the individual components and are unchanged. Since the value assignment and traceability are not affected by the repackaging, the traceability is documented by reference to K150226, K130236, K980135, K130415, K051928 and K051968.

7.4 Value assignment

The assigned values for each of the parameters are transferred unchanged from the labeling of the individual components to the Verification Kits. Since the value assignment is not affected by the repackaging, the value assignment is documented by reference to K150226, K130236, K980135, K130415, K051928 and K051968.

8 Conclusion

The Verification Kits (listed below) are substantially equivalent in intended use, fundamental scientific technology, features, and characteristics to the predicate device Validate GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Set (K091225).

Verification Kits included in this 510(k):

- VK-3 Verification Kit
- VK-4 Verification Kit
- VK-R5 Verification Kit
- VK-R7 Verification Kit
- VK-Crea Verification Kit